The Adaptable Knee Brace

Senior Project II

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Abstract [AvC & JW]

Elderly patients with osteoarthritis in the patellofemoral and lateral femoral region in the knee joint develop irregular gait from impairment mobility from pain and weakening of the muscles around the knee. For proper gait rehabilitation of the knee, a patient requires customized rehabilitation training combined with a force-assisted brace. The Adaptive Knee Brace is designed to meet these criteria as an assistive knee brace to successively alter the patient's gait in order to mitigate factors leading to impaired mobility. The device reduces the excess load on the knee based on the angle of the knee through the gate cycle. The electronic components of the brace include an accelerometer, a gyroscope, a magnetometer, and a high torque servo motor to monitor and limit the knee position throughout the gait cycle. These components provide accurate measurements and proper feedback in the knee for the desired gait angles during the rehabilitation process. The year-long project will result in a knee brace that will increase motion in the patient's knee during the swing and stance phases in their gait cycle and an overall reduction in contact forces in the areas most affected by knee OA of the end-user post-rehabilitation.

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Team Management [JW]

Avneet Chawla - BME

Avneet was responsible for co-designing and testing the load-bearing components of the knee brace. He designed the control system needed for the integration of electrical components in the brace and was responsible for gait analysis and brace optimization through video data acquisition. He also assisted in running the brace through several max stress, deformation, and shear stress in FEA analysis. He was responsible for the manufacturing, verification and validation testing, and data analysis of the prototype through statistical analysis. Finally, he often held group members accountable for their roles and productivity during group meetings.

Justina Walck - BME

Justina was responsible for managing all of the design control activities, including: upholding the timeline for the project, writing an IRB, a 510(k), a broader impact statement, the verification/validation protocols and the completion reports for the protocols. Additionally, she was responsible for managing the testing and analysis for the prototype. Lastly, as the team scribe, she was recording the steps of the design process, organizing all of the team's documents, assignments, research, etc., and adding final revisions to all of the design process decisions made throughout the project.

Karl Devoe - BME

Karl was also responsible for a large portion of the mechanical components for this project. Specifically, he was responsible for the SolidWorks designs, manufacturing a working prototype of the device, and working with the rest of the team on running FEA analysis for the design. Karl was also responsible for the budget on this project, ensuring that the project stayed within the allotted budget for prototyping and troubleshooting. He executed the testing and analysis with the team for the prototype, verifying that it met the device requirements and specifications, and the device functioned as intended. Lastly, Karl assisted with development of the electrical components and running the FEA analysis for the device.

Alex Carideo - ECE

Alex specialized in identifying and developing the necessary electrical and sensing components for the device. Specifically, Alex was responsible for designing the control unit and processing board, identifying and developing sensor devices to collect data on the angles and forces on the knee during a walking gait cycle, and interpreting this data to identify the necessary specifications, thresholds, and constraints for the device. Alex also assumed the role of webmaster for the group, where he created and maintained an updated webpage for the project.

Introduction [JW]

Knee injuries are very common, often resulting in sprains/tears of the soft tissue surrounding the knee. One of the most common knee injuries seen in the elderly community is knee osteoarthritis, which is commonly accompanied with knee pain, and can inhibit the proper walking motions of the knee depending on severity. The goal of The Adaptive Knee Brace is to design an assistive knee brace for elderly patients with severe osteoarthritis in the knee joint. The device will be targeted towards elderly patients between the ages of 60 to 90 years old, as they are a higher risk group for severe knee osteoarthritis. Since gate rehabilitation is a common rehabilitation method for patients with severe knee osteoarthritis, the assistive brace will be designed with the motions of gate rehabilitation in mind. In order to allow this brace to assist in the gate rehabilitation cycle, it will reduce the varying loads and contact forces on the knee (based on the angle of the knee through the gate cycle) which in turn should reduce pain in the knee joint. Additionally, the device will require less strength from the patient's muscles surrounding the knee in order to bear the given load of the user, which will allow the patient to perform gate rehabilitation easier with less pain and better motion. Current devices on the market are mainly used for stability assistance, whereas the Adaptive Knee Brace is designed to assist in gait cycle rehabilitation. As a result, the Adaptable Knee Brace can fill the gap in the market for elderly patients with knee osteoarthritis so they can increase their mobility and get up and active again.

Chapter 1: Background [JW]

Knee osteoarthritis (OA) is the degeneration of the articular cartilage in the knee joint. There are two types: primary and secondary. Primary osteoarthritis typically occurs with no clear underlying reason, whereas secondary osteoarthritis primarily occurs due to an abnormal concentration of force across the joint, injury, or other abnormalities in the articular cartilage (seen in Figure 1 below) [1].

Figure 1. Normal vs. Osteoarthritis Knee Joint Spacing. Normal joints have cartilage between the femur and tibia to reduce contact of the knee bones. Note: Knee osteoarthritis creates wear on this cartilage allowing bone on bone contact which creates pain and discomfort [2].

OA is usually a progressive disease that can eventually lead to disability, such as inhibiting the gate cycle in patients with severe knee osteoarthritis. Common signs and symptoms include, but are not limited to: knee pain with a gradual onset that worsens over time, knee stiffness and swelling, pain after prolonged sitting/resting, worsening pain and swelling with inactivity, and a reduced range of motion [1]. Some modifiable risk factors include: muscle weakness and imbalance, repetitive knee bending, and obesity. Knee osteoarthritis can be treated, however there are currently no proven or approved curing agents for knee osteoarthritis. Common treatments include: medication, physical therapy, knee bracing, corticosteroid injections, and surgery if the conservative treatments fail [1].

Rehabilitations tend to be used to help sedentary patients learn to walk again with a proper gate cycle to help ease the swelling and pain experienced during rest. Rehabilitations tend to be used more on elderly patients due to a more sedentary lifestyle. However, people of any age can develop osteoarthritis and depending on their situation, may require rehabilitation as well. Gait rehabilitation is the therapy used to help a patient relearn how to walk again after sustaining an

injury or disability. Gait rehabilitation is used to help strengthen the muscles around the knee, and to improve stability so the patient can perform the proper phases of the gait cycle (seen in Figure 2) [3].

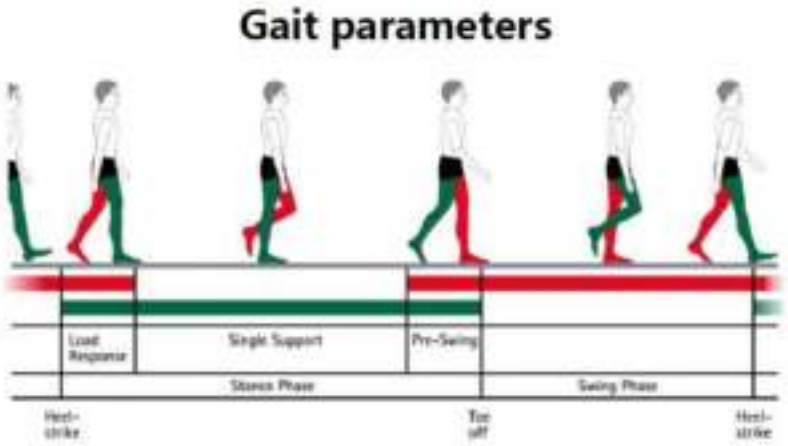


Figure 2. Phases of the Gait Cycle for Walking. The Phases of the Gait Cycle consists of two primary phases called the stance phase and the swing phase. The stance phase consists of initial contact, loading response, mid-stance, terminal stance, and preswing, The swing phase consists of the initial swing, midswing, and terminal swing [4].

Currently there are many knee braces on the market for knee osteoarthritis, however most are spring loaded, have limited adjustability, and restrict the movement speed of the wearer [5]. There are a limited number of knee braces currently on the market that allow for easy adjustment allowing for more diagnostic degrees of assistance to the user, which would help adjust the level of assistance and support needed by the brace for each individual patient (Note: this can also be used to vary the level of assistance for a single patient as they progress through the rehabilitation process).

By the age of 60, about 9.29% of the United States population are diagnosed with knee osteoarthritis (OA), affecting around 9.3 million US adults [5]. The estimated lifetime risk for patients diagnosed with knee OA was about 13.83% as of 2008, with the largest percentages affecting obese females followed by non-obese males [5]. Since there is no cure to knee osteoarthritis, treatment is typically required to reduce the patient's symptoms [5]. However, these treatments are not always effective, and oftentimes the patient will require long-term medication or invasive treatments, such as a total knee replacement, to manage their symptoms. A non-invasive treatment that does not require long-term medication is in high demand, and the Adaptable Knee Brace aims to fill this gap for patients with knee OA that are undergoing gait rehabilitation. The Adaptive Knee Brace is designed to meet these criteria as an assistive knee brace that can successively alter the gait of the patient in order to mitigate factors causing

impaired mobility. The device will reduce excess load on the knee based on the electrical sensor's recorded angles of the knee throughout the gate cycle. The design will result in an increased motion of the patient's knee during the swing and stance phases of their gait cycle, as well as reduce the overall contact forces in the areas most affected by knee OA. Since knee osteoarthritis affects a large population of the US, it is important to examine the impacts of the device economically, socially and globally.

The cost for a knee brace is relatively small when compared to the cost of surgical treatments. Based on a study performed on patients with unicompartmental osteoarthritis (UOA), an unloader knee brace, defined as a brace that removes pressure from the knee to relieve pain in the joint, costing about $870 was considered a cost-effective treatment option, with an 8-month incremental cost effective ratio of $13,350 [6]. Upon an 8 year follow up, the knee brace showed a quality-adjusted life years (QALY) gain of 0.43 and a cost-effective ratio of -$8,993 when compared with a total knee replacement (TKR) [6]. The Adaptable Knee Brace is similar to the unloader knee brace, however, in its prototype state, the cost is nearly half of that of the unloader knee brace at only $400. Both the unloader knee brace and The Adaptable Knee Brace demonstrate a cost-effective alternative to surgical treatments and has data to suggest The Adaptable Knee Brace has the potential to be a treatment method that increases the patient's QALY compared to TKR treatments. It is, however, important to note that there are no studies prior to this one that recorded the use of an unloading knee brace for longer than 5 years, and that this study that lasted 8 years used a small sample size of only 63 patients. Considering that 9.3 million US adults are diagnosed with knee osteoarthritis, a study with only 63 patients is statistically insignificant due to sampling sizes [6].

It is known that unloading knee braces provides patients with a short-term pain relief, however there has been little to no studies performed on the long term effects of an unloading knee brace [6]. Based on the same study mentioned previously, there is data to suggest that long term use of an unloading style knee brace can improve patient quality-adjusted life years (QALY), be used as a bridging therapy for surgery, and can also reduce the need for surgical intervention all together [6]. The study concludes that patients who wear an unloader knee brace for two years or more can remove the need for surgical intervention all together. Socially, this provides a higher quality life for the patient, and more mobility for the patient since they do not require bed rest post surgery. However, although being a widely debated topic, some studies suggest that such braces may be the cause for recurring knee injuries, especially in athletes, because the brace can actually weaken the natural knee stability muscles with long term usage due to reliance on the brace for support. Braces like The Adaptable Knee Brace are known to clinically reduce knee translation and rotation during low-load testing, and replicate healthy knee stiffness in a weakened knee [7]. Since rehabilitation braces are only used at most a few times per week for physical therapy/gait rehabilitation, the negative effects seen in long term use of knee braces is minimized. A physical therapist is able to provide professional supervision of the patient's overall health and knee

improvements, which can be beneficial to the patient when compared to a surgical treatment which required the patient to rest at home for weeks, potentially causing muscle degeneration, knee cramping, and other discomforts associated with being bed ridden. The Adaptable Knee Brace provides patients with a way to alleviate the pain associated with knee OA while living their life more mobile and more comfortable, all while continuing to strengthen their knee and work towards recovery.

Globally, the knee brace market has been growing due to the prevalence of knee osteoarthritis and athletic injuries [8]. As the number of sports injuries increase, the awareness surrounding athletic injuries increases, increasing the demand for preventative devices for use during athletic activities. Additionally, in older age populations, arthritis is much more common, and thus knee braces are in higher demand to treat symptoms, such as pain and stiffness. The global knee brace market is often split up into four categories: product type, application, end-user, and region [8]. The Adaptable Knee Brace is a mix between an unloader knee brace and a rehabilitation knee brace for knee OA. It is projected that the arthritis category of these braces will dominate the market worldwide due to the rise in arthritis type injuries worldwide. The end-user category is shown to have a significant demand in clinics, due to visits from patients with arthritis [8]. This tends to increase the hospitalization demand as well, due to further injuries experienced by the clinic groups. Regionally, the knee brace market is spread out around the world, but is most prominent in North America, followed by Europe and the Asia Pacific [8]. In North America specifically, the increase in cases of knee osteoarthritis in older age-groups is the major cause of demand for unloading and rehabilitative knee braces [8]. Companies such as Mueller Sports Medicine, Inc., DJO Global, LLC, (Donjoy), ACE Brand, Tynor Orthotics Private Limited 3M Science, Mava Sports, Bauerfeind AG, Breg, Inc., and Ossur are some of the largest globally operating knee brace companies on the market [8].

Together, these companies, along with other smaller companies, operate to provide various types of knee braces around the world. With the US being the highest in demand for knee braces, due to sports and the rise in arthritis in the elderly communities, the significance for a brace that can be used to bridge, or replace, total knee replacement surgeries all together are in high demand. Studies have shown that brace therapies increase the patient's QALY compared to TKR, and are more cost-effective therapies when compared to surgical treatments. The Adaptable Knee Brace has the potential to further fill this gap in the market, and move the world one step closer to a cost-effective, non-invasive treatment for knee osteoarthritis.

Most of the currently marketed knee braces are designed to assist the patient using supportive and stabilizing techniques, however, they provide limited assistance to the patient in actually executing the gait cycle motions for gait rehabilitation. The Adaptable Knee Brace is a viable option for a rehabilitative knee brace that assists patients throughout their gait cycle by

potentially improving the patient's knee range of motion as well as by correcting the patient's knee angles throughout the rehabilitative cycle.

Chapter 2: Design Inputs [JW & AvC]

Requirement 1: Size & Fit [JW & AvC]

The first design requirement is that the device must be able to fit the leg of the device user. The average user is both male and female over the age of 65 with thigh circumference of 48.0 ± 5.6 cm^2 as well as average calf circumference of 32 ± 3.2 cm^2 [9] . The device must be able to accommodate a wide range of both the upper and lower half of the leg circumferences in the targeted age range.

Requirement 2: Load Capacity [JW & AvC]

The next device requirement is that the device must be durable enough to withstand the weight from the average device user. The average user is both male and female over the age of 65 with weights of 72kg and 65kg [10]. The device must also support the weight of an average person during movements with high joint forces such as jumping and sprinting. In order to accommodate the average wear of the device, the device must be able to support three times the body weight of the average male during high-stress activities to avoid breaking during use [10]. Three times the average body weight accounts for the highest stresses during activities with high joint forces such as jumping and landing.

Requirement 3: Hyperextension Prevention [JW & AvC]

The device must be able to provide internal resistance to prevent hyperextension of the knee. Hyperextension of the knee occurs when the knee angle of a person is below 0±3° when planting the leg [11]. The brace must prevent a knee from reaching below the specified angle. If a patient's knee is hyperextended then the knee may undergo structural damage and further instability. For a patient undergoing treatment for knee osteoarthritis, stability is crucial for retaining a proper gait motion.

Requirement 4: Resistance During Flexion [JW & AvC]

The device must also provide resistance for the knee during excess flexion. The knee during flexion in the gait cycle must not exceed an angle of 60±5° (between initial and pre-swing) [11]. If the angle is greater than 60° then there is a significantly greater risk of the patient to lose balance and fall.

Requirement 5: Vertical & Rotational Motion [JW & AvC]

The device must also be able to support vertical motion due to high impact and rotational motion. The vertical allowance of impact for the device will be about 2mm and the rotational motion will be limited to an angle range of 0° to 60° [10]. The accommodation of a vertical movement of the joint during sudden force is important to avoid increasing vertical knee strain to the knee joint and increasing the amount of time the device can be used for rehabilitation. The

rotational motion of the hinge system supports a range of angles for a gait limited motion of the knee.

Requirement 6: Low Latency [JW & AvC]
The next device requirement is that the electrical components in the device must operate with a very low latency. If the average rate of the standard human is 100 steps per minute that's about 0.6 seconds per step since there are eight phases of the gait cycle of 0.6 / 8° is 75 milliseconds. Human reaction time to change their own gait is about 25 milliseconds, but the reaction time of the device should be significantly lower to make an independent impact on gait. Therefore the projected reaction time should be about 10 milliseconds to make significant adjustments based on the time interval and the proper device specifications [12].

Requirement 7: Data Recording [JW & AvC]
The device must record positional data during exercise. Recorded data should include flexion, extension, rotation, angle, speed, and steps per minute in order to properly evaluate the users gait. In order to properly evaluate gait motions and create active feedback to the patients, gait data must be acquired to analyze forces, knee angles, and other aspects of gait rehabilitation.

Requirement 8: External Moisture Shielding [JW & AvC]
The electrical components of the device must be shielded from external moisture and contaminants. The components of the device should be used in accordance with ANSI/AAMI HA60601-1-1. The protection of external electrical equipment is necessary to mitigate any hazards from external elements such as dust or sweat.

Requirement 9: Battery Duration [JW & AvC]
The device's battery must last throughout the duration of gait therapy with a trained physical therapist. The device must be powered through a full hour long session of gait rehabilitation as is standard for most gait rehabilitation sessions [14]. If the battery does not last longer for a session then the data collection and feedback will become harder to access and will reduce the efficacy of the brace.

Requirement 10: Comfort [JW & AvC]
Another device requirement is that the device must be comfortable for patients during use. Device comfort is very important while assisting and supporting the user. Comfort of the device can be measured by the amount of hindrance or reduced motion capability by the patient. Hindrance of motion is caused by tightness of the brace or incorrect material stiffness in the brace which significantly reduces the efficacy of the brace through poor blood circulation or skin irritation. However, there are no projected specifications for motion restrictions and irritations.

Requirement 11: Biocompatibility [JW & AvC]

The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993 [15]. The device is interfaced with the human body and must be classified under a category B surface device that has to pass that test for cytotoxicity, sensitization, and irritation.

Chapter 3: Design Process [AvC, KD, AlC]

Brace Fitting [AvC]

The circumference of the average users of the user's thighs and calves are 48 ± 5.6cm and 32 ± 3.2cm respectively. The fitting of the brace and the final prototype diameter of the brace was determined by both the average circumferences from the intended users and the sizing chart seen below (Figure 3). The final circumferences of the brace were 48.69cm for the thigh portion and 39.27cm for the calf portion.

Z-12 Size Chart

Size #	Size	Thigh Circumference	Standard Calf Circumference	Athletic Calf Circumference
XX = 01	XS	13.5" – 16" (34 – 41 cm)	12.5" – 14" (32 – 36 cm)	11" – 12.5" (28 – 32 cm)
XX = 03	S	16" – 18.75" (41 – 48 cm)	14" – 15.5" (36 – 39 cm)	12.5" – 14" (32 – 36 cm)
XX = 05	M	18.75" – 21.5" (48 – 55 cm)	15.5" – 17" (39 – 43 cm)	14" – 15.5" (36 – 39 cm)
XX = 07	L	21.5" – 24.25" (55 – 62 cm)	17" – 18.5" (43 – 47 cm)	15.5" – 17" (39 – 43 cm)
XX = 09	XL	24.25" – 27" (62 – 69 cm)	18.5" – 20" (47 – 51 cm)	17" – 18.5" (43 – 47 cm)
XX = 11	XXL	27" – 29.5" (69 – 75 cm)	20" – 21" (51 – 53 cm)	18.5" – 20" (47 – 51 cm)

Thigh circumference measure 6" (15 cm) above mid-patella. Calf circumference measure 6" (15 cm) below mid-patella. Brace length: Standard 13" (33 cm), Extended 15" (38.1 cm).

Figure 3. Generic Size Chart for Knee Braces [16]

In order to implement a cheap, finely adjustable, and reusable fitting aparatute several materials were considered. The best of these materials which met all the criteria was velcro straps due to their ability to be cut and mounted onto the knee brace.

Double Hinge Mechanism [AvC]

A double hinge design is important to consider over a single due to its ability for simultaneous vertical and rotational motion of the brace. Vertical motion in the knee for patients with abnormal gait allows for the proper distributions of knee strain during steps with large forces such as those induced by running or jumping. Proper rotational motion is key to provide angular changes in the brace without infringing on the natural motion of the knee joint. The hinge mechanism consists of:

1. The backplate which helps prevent the user from injury while also providing a secure place to mount the rest of the mechanics to
2. Five 2.5mm threaded bolts composed of 316 Stainless steel to hold the assembly together
3. Two shorter rounded plates to connect the thigh and calf portions of the brace to each other creating the "first" hinge mechanism
4. Spacers to provide spacing between the thigh and calf portions of the knee brace and the back plate and front plate of the hinge
5. A front plate which provides the "second" hinge mechanism

6. A flapper and wedge mechanism in which the wedge attaches to the servo to restrict angles in the brace

The final hinge design can be seen in Figure 4 below.

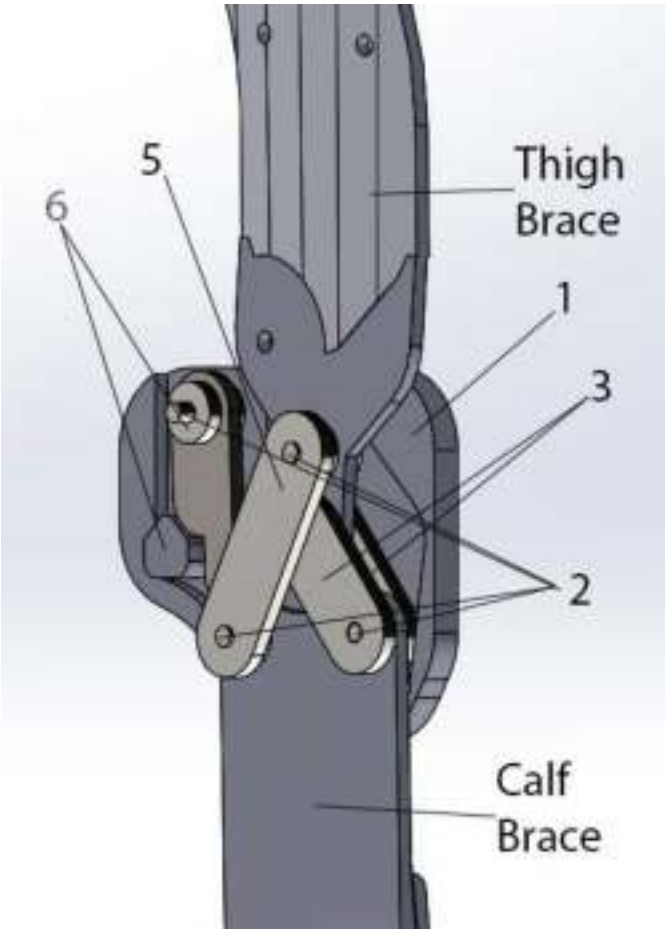


Figure 4. Brace Hinge Design

There is an additional part shown below attached to the back plate of the hinge. The servo mounting plate that holds together the wedge mechanism, mechanically prevents hyperextension, and provides a place for the server to mount to (Figure 5).

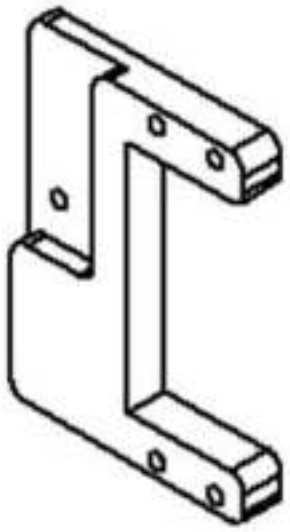


Figure 5. Drawing of the ¼” 6061 Aluminum Mounting Plate for the High Torque servo motor

Mechanical Brace Materials [AvC]

The materials used in the brace were 6061-T6 aluminum and 316 Stainless Steel bolts. ⅛” 6061-T6 aluminum sheets were used in the manufacturing of the thigh portion, calf portion, spacers, and connecting plates used in the hinge while the backplate and the servo mounting plate of the hinge was machined out of ¼” 6061-T6 aluminum. 316 stainless steel bolts were used to assemble the hinge mechanism and to attach the velcro straps to the brace. This was chosen both due to its material properties and availability. 6061 Aluminum was chosen over Steel 316 due to its relative cost for the amount of material we required within our budget, its reduced weight for the thickness it attains, and its machinability. Aluminum 6061 T6 was run through the water jet with relative ease but the difference in manufacturing was when the CNC machine was manufacturing the back plate. The thickness required for the brace when using steel 316 would have had a higher risk of damaging the machine and delaying the timeline of the prototype. The Aluminum 6061 was also rolled to produce the desired diameter for the average leg in the table above, the steel would take considerably longer to roll or bend to the desired diameter due to its added rigidity.

Electronics Block Diagram [AlC]

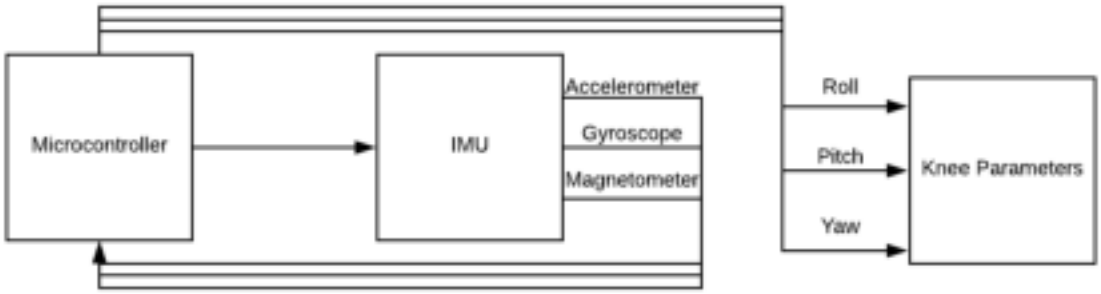


Figure 6. Electronics Block Diagram

This is a block diagram of the electrical portion of the brace which details the transfer of data from the inertial sensors to the microcontroller. This data is used to calculate the rotation of the brace in the x, y, and z direction. This is the roll, pitch, and yaw of the brace through the walking gait cycle which will be used to analyze and adapt the brace to the user's gait cycle for rehabilitation.

Microcontroller [AlC]

The microcontroller that is used in the design is the Arduino Nano 33 BLE. This microcontroller is pictured in Figure 7 and has the following technical specifications in Table 1.

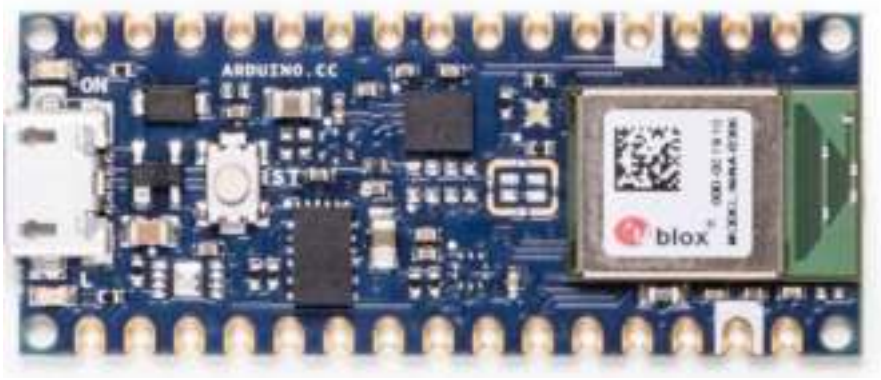


Figure 7. Arduino Nano 33 BLE

Table 1: Microcontroller Technical Specifications

Mircocontroller	Dimension (mm)	Operating Voltage	Current Draw	Clock Rate	Pins	Communication Interface	Additional Features
Arduino Nano 33 BLE[21]	45 x 18	3.3V or 5V	< 20mA	64MHz	16 Digital 9 Analog	IC2 SPI	Onboard IMU
Raspberry PI 4	85.6 x 56.5	3.3V or 5V	< 500mA	1.5GHz	40 GPIO	IC2 SPI	N/A
Teensey 3.2	30 x 18	3.3V or 5V	< 50 mA	96MHz	34 GPIO	IC2 SPI	N/A

This is a decision matrix detailing the technical specifications of the microcontrollers considered for the design including Arduino, Teensy, and Raspberry PI models. Technical specifications between these microcontrollers were evaluated including dimensions, price, interfaces, current draw, operating voltage, performance, and additional features as shown in Table X. All the microcontrollers fit within the dimension and cost ranges, the battery pack can supply sufficient operating voltage and current draw, and they all have compatible communication pin interfaces with the inertial sensors. The most significant difference between these microcontrollers is the processing speed with the Raspberry PI being far superior and the onboard inertial feature of the Arduino Nano 33 BLE. The benefit of the Arduino Nano's onboard inertial sensor meant that only one additional inertial sensor would be added to the design which would significantly reduce the cost and complexity of interfacing between multiple inertial sensors. For these reasons the Arduino Nano 33 BLE was chosen as the most optimal microcontroller for the design. This inertial sensor provides much more ease of design and a more affordable option because only one additional inertial sensor would be purchased.

For the project design, this microcontroller handled processing of sensor data into pitch, roll, and yaw angles using an algorithm as discussed further in the inertial mass unit section. The sensors were placed on the side of the brace meaning that the yaw angle corresponded to the knee angle during the walking gait cycle as discussed in the results section. The microcontroller also controlled the servo motor mechanism to limit the degree of rotation of the brace which will be discussed later in the servo motor section.

Inertial Mass Unit [AlC]

The inertial measurement unit (IMU) is an electronic device that measures acceleration, angular velocity, and orientation through the use of gyroscopes, accelerometers, and magnetometers. Utilizing an IMU's accelerometer and gyroscope outputs will allow for calculation and outputting of roll, pitch, and yaw angles as a source of positional data on the users knee during

the walking gait cycle. Figure 8 details the planes of movement for the roll, pitch, and yaw angles.

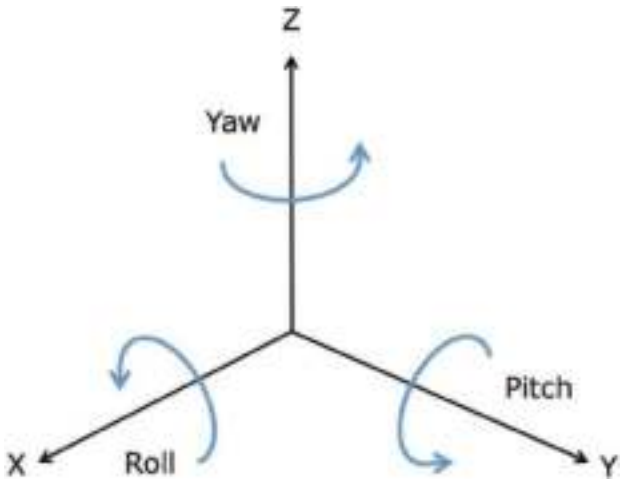


Figure 8. A representation of three dimensions of movement when an object moves through a medium.

To calculate the roll, pitch, and yaw position of the sensor the Madgwick Filter was used. This is a complementary mathematical filter that uses a combination of accelerometer and gyroscope data to determine the roll, pitch, and yaw. Ideally assuming the sensor is perfectly still in a set position with no factors of linear acceleration the roll, pitch, and yaw can be calculated using the following algebraic expressions [17]:

$$Roll = \frac{180}{\pi}\tan^{-1}\left(\frac{Y}{\sqrt{X^2 + Z^2}}\right)$$

$$Pitch = \frac{180}{\pi}\tan^{-1}\left(\frac{X}{\sqrt{Y^2 + Z^2}}\right)$$

$$Yaw = \frac{180}{\pi}\tan^{-1}\left(\frac{Z}{\sqrt{X^2 + Z^2}}\right)$$

To make the calculations for roll, pitch, and yaw more accurate a combination filter is used to eliminate some linear acceleration factors. This makes the calculations more accurate because during gait testing the sensors are moving through the walking gait cycle. The filter used is the Madgwick Filter which uses a mathematical model of the inertial mass unit sensor and a combination with accelerometer and gyroscope data to calculate the roll, pitch, and yaw. The Madgwick Filter also uses a quaternion representation to calculate the orientation of the device [18].

The overview of this filter is illustrated in the following figure.

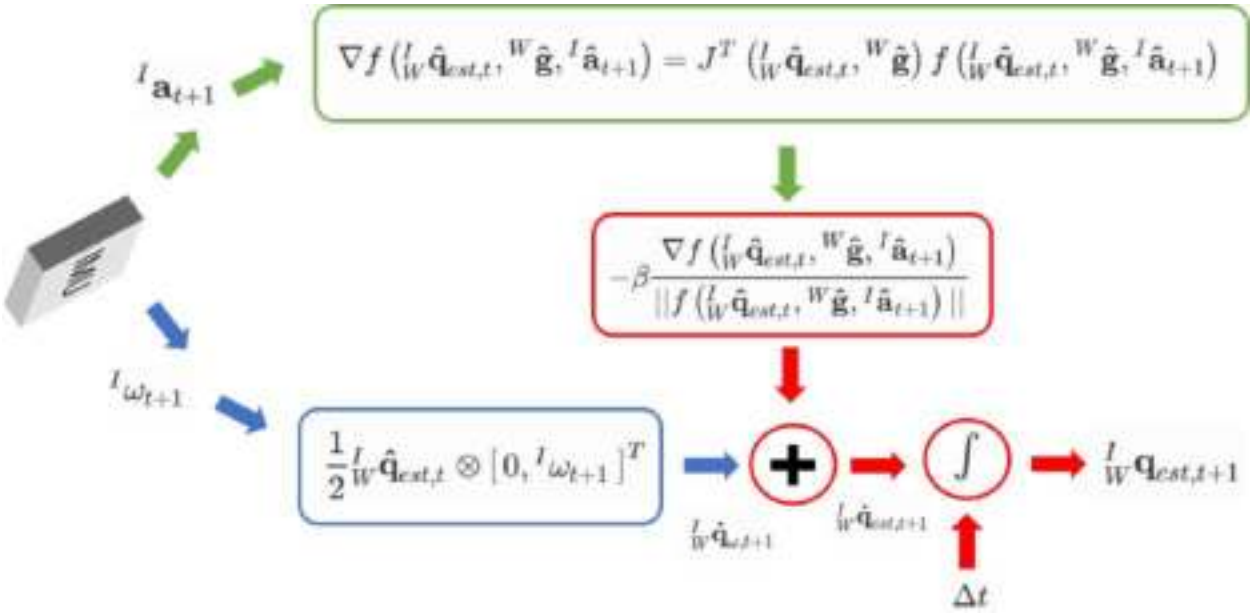


Figure 9. Overview of the Madgwick Filter

Figure 10 shows the gyroscope and accelerometer measurements are denoted as I_{wt} and I_{at}. Next to compute the factors of acceleration the quaternion representation is used:

$$\nabla f\left({}^{I}_{W}\hat{\mathbf{q}}_{est,t}, {}^{W}\hat{\mathbf{g}}, {}^{I}\hat{\mathbf{a}}_{t+1}\right) = J^{T}\left({}^{I}_{W}\hat{\mathbf{q}}_{est,t}, {}^{W}\hat{\mathbf{g}}\right) f\left({}^{I}_{W}\hat{\mathbf{q}}_{est,t}, {}^{W}\hat{\mathbf{g}}, {}^{I}\hat{\mathbf{a}}_{t+1}\right)$$

$$f\left({}^{I}_{W}\hat{\mathbf{q}}_{est,t}, {}^{W}\hat{\mathbf{g}}, {}^{I}\hat{\mathbf{a}}_{t+1}\right) = \begin{bmatrix} 2\left(q_2 q_4 - q_1 q_3\right) - a_x \\ 2\left(q_1 q_2 + q_3 q_4\right) - a_y \\ 2\left(\frac{1}{2} - q_2^2 - q_3^2\right) - a_z \end{bmatrix}$$

$$J\left({}^{I}_{W}\hat{\mathbf{q}}_{est,t}, {}^{W}\hat{\mathbf{g}}\right) = \begin{bmatrix} -2q_3 & 2q_4 & -2q_1 & 2q_2 \\ 2q_2 & 2q_1 & 2q_4 & 2q_3 \\ 0 & -4q_2 & -4q_3 & 0 \end{bmatrix}$$

Figure 10. Orientation based upon acceleration measurements

The update term related to the acceleration measurements is denoted as:

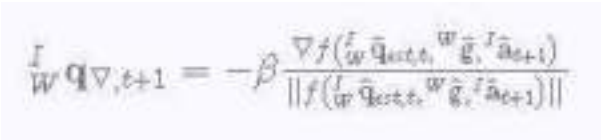


Figure 11. Acceleration update factor

Next to compute the gyroscope measurements using the quaternion representation the following formula is used:

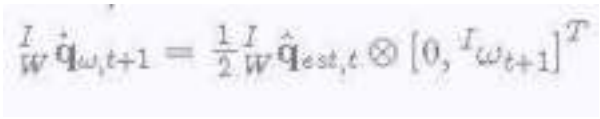


Figure 12. Gyroscope measurement factor

Finally the filter combines the to get a more accurate measurement for attitude in the roll, pitch, and yaw planes over time resulting in the following quaternion factors:

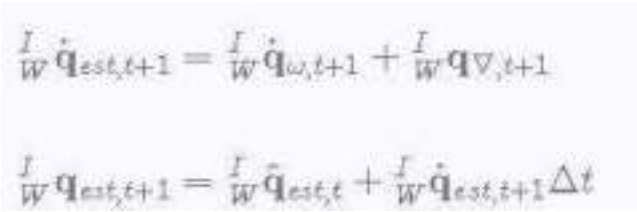


Figure 13. Attitude Factors

The reason why this filter was implemented in the design was because it gave more accurate results for yaw, pitch, and roll positions and was easy to implement using the arduino library for the Madgwick Filter.

The sensor used in the design and onboard the microcontroller is the LSM9DS1 which incorporates a triple-axis accelerometer, gyroscope, and magnetometer. This creates 9 degrees of sensing with the accuracy ranges listed in Table 2 below.

Table 2: Sensor Ranges for Accelerometer, Gyroscope, and Magnetometer in LSM9DS1

Accelerometer	Gyroscope	Magnetometer
±2/±4/±8/±16 g ranges	±245/±500/±2000 dps ranges	±4/±8/±12/±16 gauss ranges.

Servomotor [AlC]

The servo motor used in the design was the ANNIMOS 20KG High Torque Digital Servo Motor. This servo was used because the brace required high torque to stabilize the mechanism at different angle restrictions. The servo has the following properties:

- Upgraded Version - advanced linearity and accuracy with precision potentiometers,stable,low noise,water-proof
- Large Torque - maximum torque is up to 21.5 kg/cm (298.5 oz/in)@6.8V
- High Quality - equipped with strong copper & aluminum gears,CNC aluminium middle Shell
- High Rotation - well-controlled, 270 degree rotation. 360 degree rotation when power-off, perfect for robot joint activities
- Dimensions - 1.58x0.79x1.60inch (40x20x40.5mm);Weight: 60g (2.12oz) only

The servo mechanism was used to limit the degree of rotation of the brace. For the brace restriction we chose 3 different degrees of restriction 2-30 degrees, 2-50 degrees, and 2-88 degrees. The brace was tested at these different restrictions which allowed us to see the changes in the user's gait which we will discuss later (Figure 14).

Figure 14. The servo is attached to a threaded string which controls the slider (not seen) for controlled angle restrictions

Battery Pack [AlC]

The battery pack must be sufficient to power the brace for the period of gait analysis and rehabilitation. The microcontroller and inertial mass units can use a 3.3V voltage power supply in which the lithium-ion battery pack with a 3.7V voltage output is sufficient. The current draw current from the inertial sensors is approximately 10mA so with a 6600 milliamp-hour battery capacity the battery will be able to operate the device for 27 and a half days. The lithium-ion battery pack is also rechargeable so the device could be recharged during periods of non-use by the user which will extend the use of the device.

$$Battery\ Life = \left(\frac{6600mAh}{10mA}\right)\left(\frac{1\ day}{24\ h}\right) = 27.5\ days$$

GUI [AlC]

Ideally the design would include a bluetooth application to provide the user with an easy way to access the patient's gait and ultimately find the ideal brace restriction setting to correct the patient's gait. For this application a generic graphic user interface was designed that would communicate and transfer data from the brace over bluetooth. This graphic user interface was made using MATLAB Application Designer and is shown in Figure 15.

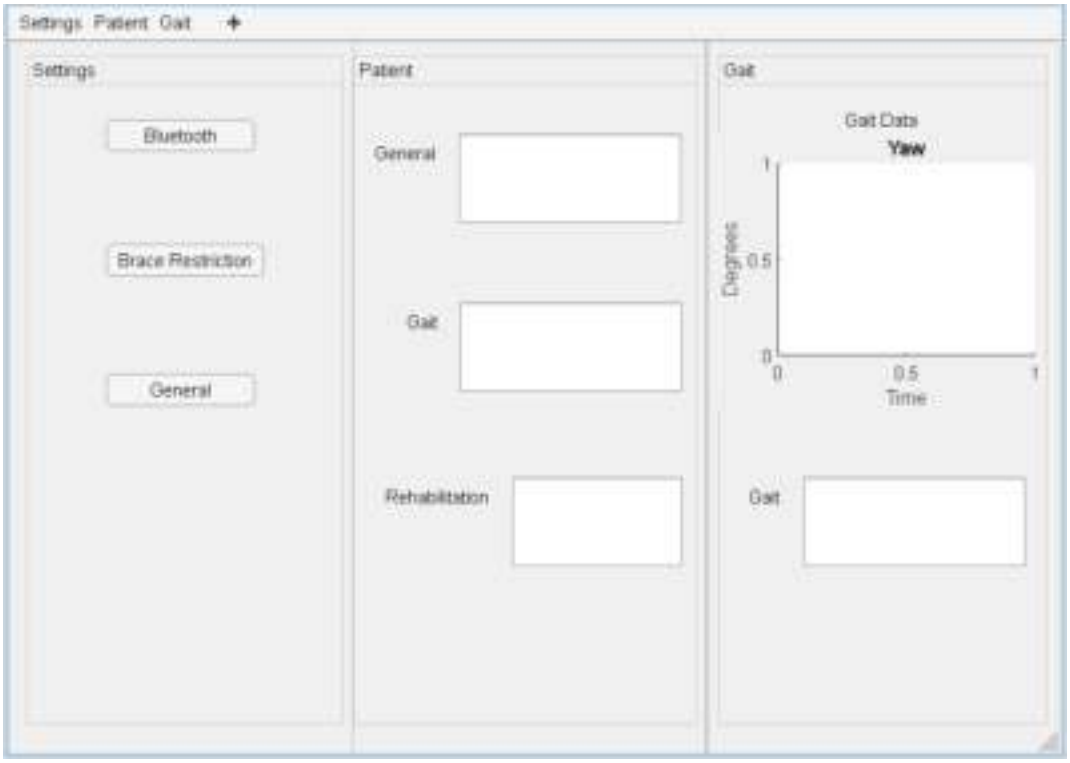


Figure 15. Graphic User Interface

This interface includes three menus as shown. The first menu is for settings where the user would be able to connect to the brace over bluetooth, view any general application settings, and change the brace restriction. The second menu details all the patient's information including any general information on the patient, and information about their gait that would be useful for the user to understand, and an individualized rehabilitation program for the patient. On the third menu a live data collection is shown of the user's gait while the software determines the adequate brace restriction by analysing the patient's gait data compared to a programmed ideal gait.

Chapter 4: Final Design [KD, AvC, & AlC]

The mechanical portion of the final prototype design consisted of the thigh and calf portions along with the double hinge mechanism. The double hinge mechanism is mounted with steel 316 pins and is placed on the backplate. The backplate is the housing unit for the hinge system and the slider to restrict the angles. The sliders will be wedged into the side of the backplate in order to restrict the angles. The slider is controlled through the servo arm at programmed angles. The designed GUI allows the PT to program the device to the specifications for each patient. The GUI also creates an easy way to access the patient's gait and ultimately find the ideal brace restriction setting to correct the patient's gait. The only modification made to the design post simulation is that it was found that the flapper and wedge components along with the servo and servo mount were only needed on one side of the brace. This allowed for both a cheaper overall cost and a more comfortable design for the user. The final mechanical design can be seen in Figure 16.

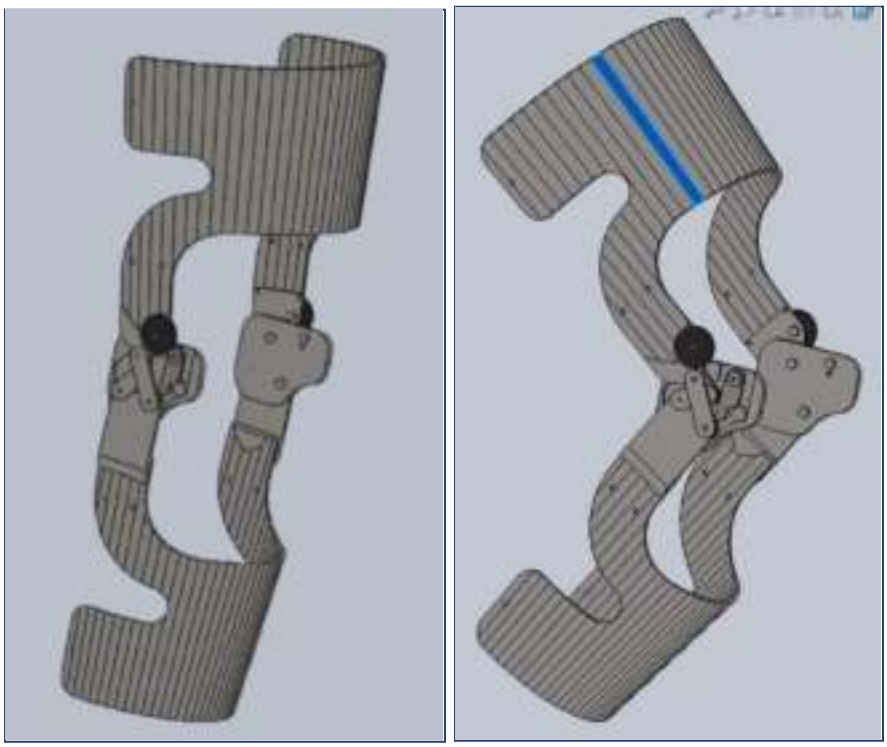


Figure 16. Final Solidworks Design

The Arduino Nano 33 BLE Microcontroller interfaced with the LSM9DS1 inertial sensor using I^2C communication. The microcontroller was placed on the upper portion of the brace while wires connected the LSM9DS1 sensor at the bottom portion of the brace. This was so data on the gait could be collected at the thigh portion and calf portion of the leg. The microcontroller was also connected to the servo motor near the hinge portion of the brace to adjust the brace

restriction. The battery pack was then used to power the microcontroller, servo, and sensor. The final prototype can be seen in Figure 17.

Figure 17. Final Design Prototype

Chapter 5: Verification Testing [AvC, KD, & AlC]

Size and Fit [AvC]

As per requirement 1 of the design inputs the brace had to be able to fit the average intended user with a thigh circumference of 48 ± 5.6 cm and a calf circumference of 32 ± 3.2 cm. These averages were then compared to a sizing chart which was available for a brace which was on the market (Figure 3).

Z-12 Size Chart

Size #	Size	Thigh Circumference	Standard Calf Circumference	Athletic Calf Circumference
XX = 01	XS	13.5" – 16" (34 – 41 cm)	12.5" – 14" (32 – 36 cm)	11" – 12.5" (28 – 32 cm)
XX = 03	S	16" – 18.75" (41 – 48 cm)	14" – 15.5" (36 – 39 cm)	12.5" – 14" (32 – 36 cm)
XX = 05	M	18.75" – 21.5" (48 – 55 cm)	15.5" – 17" (39 – 43 cm)	14" – 15.5" (36 – 39 cm)
XX = 07	L	21.5" – 24.25" (55 – 62 cm)	17" – 18.5" (43 – 47 cm)	15.5" – 17" (39 – 43 cm)
XX = 09	XL	24.25" – 27" (62 – 69 cm)	18.5" – 20" (47 – 51 cm)	17" – 18.5" (43 – 47 cm)
XX = 11	XXL	27" – 29.5" (69 – 75 cm)	20" – 21" (51 – 53 cm)	18.5" – 20" (47 – 51 cm)

Thigh circumference measure 6" (15 cm) above mid-patella. Calf circumference measure 6" (15 cm) below mid-patella. Brace length: Standard 13" (33 cm), Extended 15" (38.1 cm).

Figure 3. Generic Size Chart for Knee Braces [16]

Using this chart it was decided that the brace should be machined to fit a thigh diameter of 48cm and a calf diameter of 39cm. After machining the brace the final dimensions had an upper thigh diameter of 15.5cm and a lower calf diameter of 12.5cm resulting in a thigh circumference of 48.69cm and a calf circumference of 39.27cm. These brace dimensions paired with the adjustable velcro straps allowed for the brae to fit our intended user along with users slightly larger and smaller then our intended average user.

Load Capacity [KD]

For the load capacity testing the brave model was imported into Ansys workbench for Finite Element Analysis (FEA) testing. To do this, the 3D model was exported from Solidworks as an ".igs" file. The file was then imported into Spaceclaim and saved as a ".scdoc" file to be used in Ansys workbench. The automatically generated party contacts were then deleted and automatically generated joints were implemented. The 3D model file was then run in a Rigid Dynamics system analysis for total deformation, Normal stress, and shear stress with the model supports being the two main pins of the double hinge mechanism. Forces were added in both the screenshot of each output taken and the maximum force from the simulation was compared to the material properties of the brace components.

For the average intended user force analysis the maximum normal force was 1.54MPa in the calf portion of the brace and the maximum shear force was 1.24MPa which was in the main two bolts of the hinge mechanism. The maximum forces were then compared to the yield stress of both materials which are 276MPa for the 6061-T6 Aluminum and 205MPa for the 316 stainless steel

bolts. It was determined that since these yield stresses were significantly higher then the maximum values from the simulation that the design will be structurally sound under average intended use (Figure 18 - Figure 20).

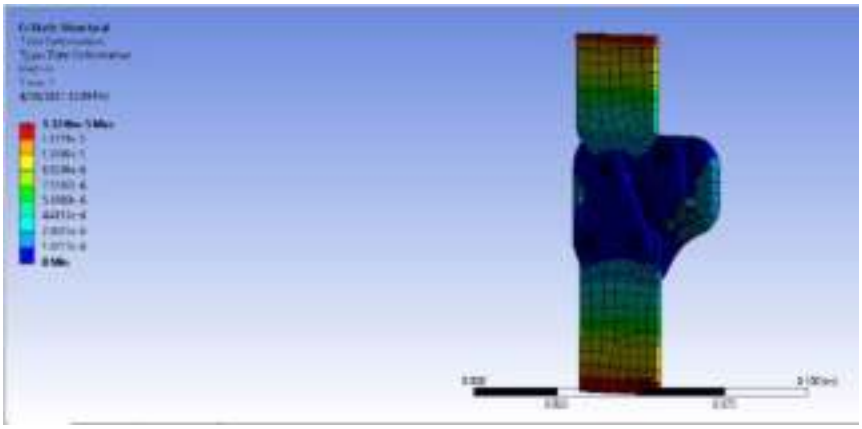


Figure 18. This figure shows the deformation of the hinge design during normal loading. The results showed a maximum of 13.2µm

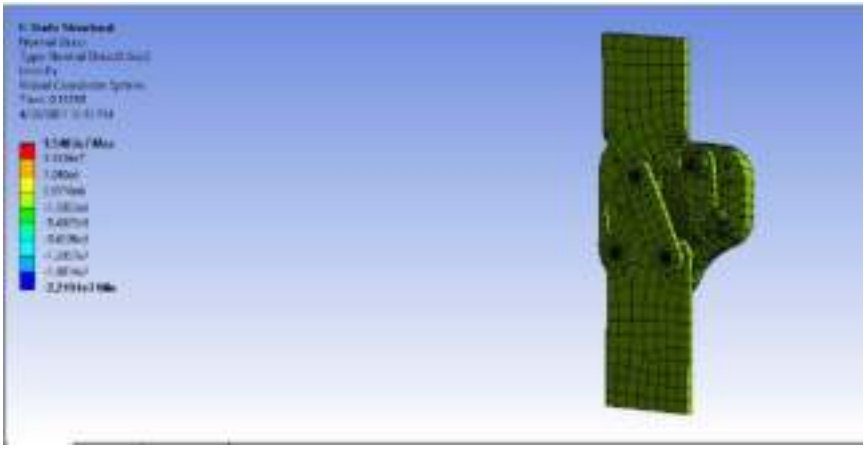


Figure 19. This figure shows the results of normal stress on the hinge design during normal loading. A maximum of 1.54MPa was seen in the calf portion of the brace.

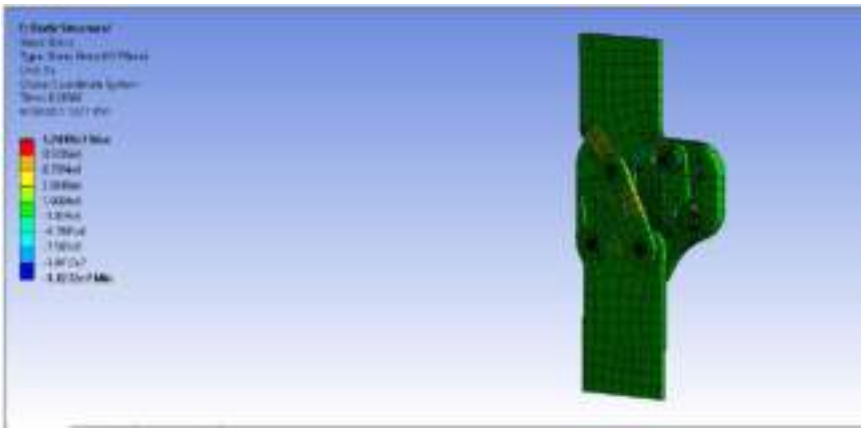


Figure 20.This figure shows the results of the shear stress of the hinge during normal loading. The maximum shear stress was on the pins holding together the hinge mechanism which had a force of 1.24MPa.

The extreme case simulation of three times the normal intended user forces (A force of 2116.8N) was run in the same way as the normal intended use force simulation with the only difference being a force of 2116.8N was used in each direction instead of 705.6N. This resulted in a maximum load of 4.62MPa which was in the calf portion of the brace and a maximum shear stress of 3.27MPa which was in the main two bolts of the hinge mechanism. These values were also compared to the yield stress of both materials which are 276MPa for the 6061-T6 Aluminum and 205MPa for the 316 stainless steel bolts. From this it was also determined that since the yield stress of the materials used were significantly larger than the maximum stress from the simulation that the brace would be structurally sound during extreme cases of at least three times the average intended user giving the brace a proven factor of safety of at least 3 (Figure 21 - Figure 23).

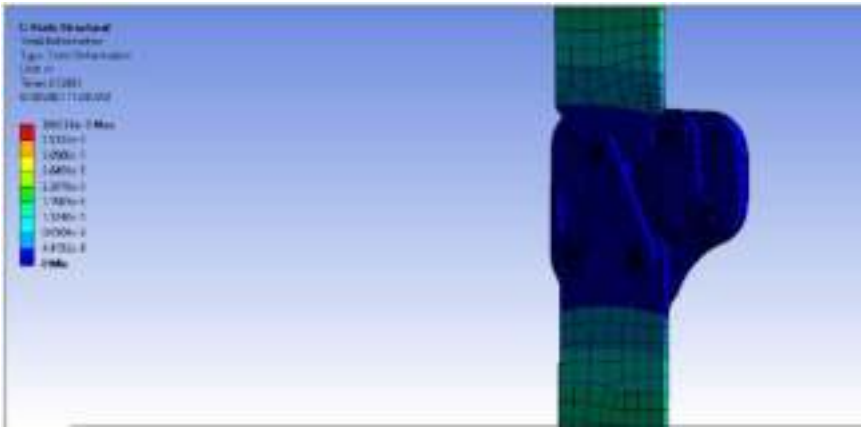


Figure 21. This figure shows the deformation of the hinge design during normal loading. The results showed a maximum of 39.8µm

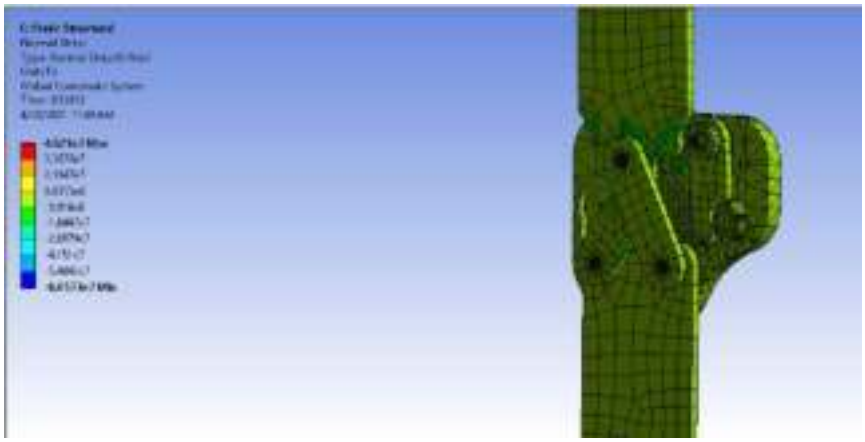


Figure 22. This figure shows the results of normal stress on the hinge design during normal loading. A maximum of 4.62MPa was seen in the calf portion of the brace.

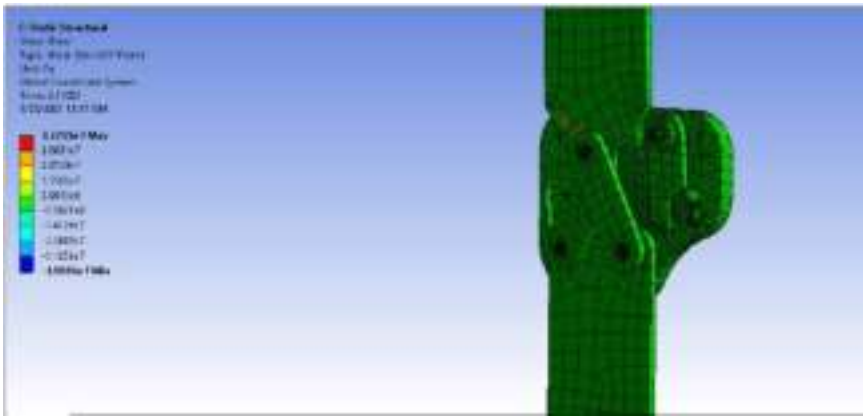


Figure 23. This figure shows the results of the shear stress of the hinge during normal loading. The maximum shear stress was on the pins holding together the hinge mechanism which had a force of 3.27MPa.

Hyperextension Prevention [KD]

One potential problem that can occur when walking is hyperextension of the knee which is when the knee. This is when the knee is bent backwards (extended) past the straight position. To prevent this the brace hinge was designed to prevent the leg from extending this far. Moreover the servo mount was designed to also prevent hyperextension which prevented extension past the 2° point which is within a normal healthy gait. To prove this a protractor was used when the brace was extended to its maximum allowed extension which confirmed that maximum extension of 2°.

Applied Resistance & Hinge Motion [AvC]

To confirm hinge motion we set the motor to the three settings. The first setting has no restriction at all during knee bending and the brace was bent mechanically to simulate natural movement during gait. The angles achieved by allowing the servo to be in a horizontal position was

measured by the magnetometer and confirmed with separate measurements by a protractor. The angle range for the no restriction from the slider mechanism on the double hinge was confirmed to be a range of 2°-88°. The angle restriction and proof of rotation was tested with two additional measurements by the magnetometer and confirmed with a protractor at angle ranges of 2°-50° and 2°-30°. The angle range was restricted mechanically within the range of 2°-88° and was further restricted with the slider mechanism pulled by a high torque servo motor (Figure 24).

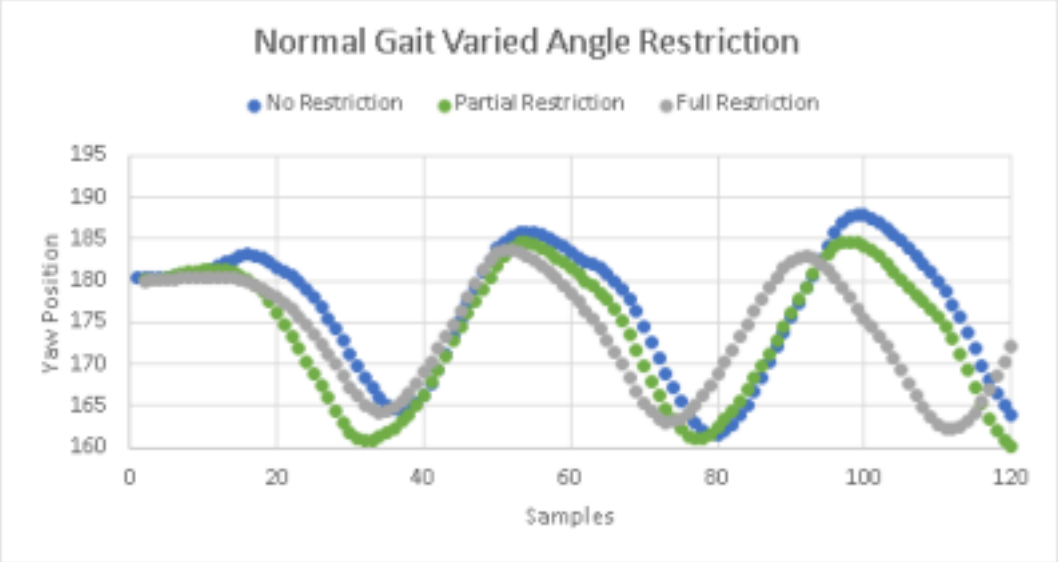


Figure 24. Normal Gait Angle Restriction Data Analysis

Low Latency [AlC]

The LSM9DS1 sensors have a variety of operating modes corresponding to different sampling rates. For low latency we wanted a sampling rate higher than 300Hz so for the accelerometer and gyroscope we chose mode 5 which has a sampling rate of 476Hz and mode 8 for the magnetometer which has a sampling rate of 400Hz. After running code to test for the sensor's sampling rate, we found that the average sampling rates for the accelerometer and gyroscope were around 463Hz and the average magnetometer sampling rate was about 420Hz. However, this verification activity ultimately failed for a sampling rate of 300Hz because when we implemented the sensors together the sampling rate used was only 104Hz. We found that this sampling rate was still sufficient for data collection and could further be improved upon in the future based on the sensors capabilities.

Battery Capacity [AlC]

The battery was tested for maximum current draw and then calculating the capacity based on the specified battery capacity. The maximum current draw from the battery was 11.8mA which means that the battery with a 6600mAh battery capacity should theoretically last for 23.305 days. A battery capacity test was also used to determine the batteries capacity. The battery was tested

before and after using the brace for one hour. This way the battery discharge rate was used to calculate battery capacity.

Data Recording [AlC]

For the data recording verification, we wanted to show that the sensors could read data. For this we ran test code to print accelerometer, gyroscope, and magnetometer data in the x, y, and z direction while moving the sensors in various directions. We then compiled the data in excel to verify data collection.

Moisture Shielding [AvC]

To test the usability of the equipment during long physical therapy sessions, the components at the highest risk of malfunctioning when exposed to external moisture or body fluids were tested. The Arduino BLE board cover with the electronics mounted inside was sprayed as data was collected and the latency data was tested before and after the spray test to test for proper functionality based on the protection. The data was compared pre and post spray using a paired t-test showing no significant difference between two instances of the three trials ($p>0.05$).

Low Current Withdraw [AlC]

Low current withdrawal was needed for the brace so that the brace is safe while operating and to test for how long the brace lasts in the battery capacity section. To test for low current withdrawal the battery was connected with the microcontroller with the brace under full operation to test for maximum current withdrawal. The maximum current withdrawal from the microcontroller was 11.8mA which is greater than the 10mA slightly larger than the requirement.

Chapter 6: Validation Testing [KD & AvC]

Fitting and Range of Motion Validation [AvC & KD]

Comfort levels were assessed by each subject while testing, and were measured via several factors. Comfort during motion assessed by making the subjects fill out a questionnaire post testing the gait. The results from the questionnaire showed the device fit the leg on 7 out of 8 people used for the test. 8 out of 8 people answered that the brace allowed them to walk without the feeling of restriction. 8/8 people answered that the brace was able to flex and extend with little to no restriction of natural movement of the knee. All of the participants also clearly stated that jumping and landing was not restricted and did not cause any discomfort. According to the quantitative table of values of comfort the average was about 4.1 / 5. Statistical Analysis was not performed during the assessment of comfort based on the specified design criteria. The Knee Brace Fit and Rotational Motion validation has been established by objective evidence that all key aspects of the Adaptive Knee Brace adheres to the approved specifications.

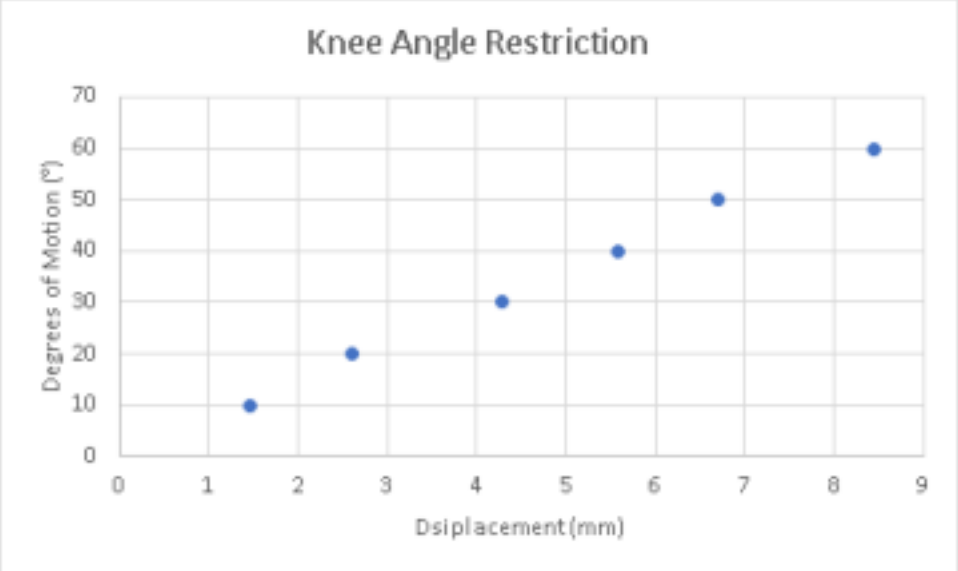
Refer to Appendix _ Sections _ and _ for the validation protocol and completion report.

Data Collection, Accessibility, and Security Validation [KD]

To increase patient security all data gathered is saved on a local drive which is accessible physically via a USB-c cable. This system allows for the data to be easily accessed by the patient or physical therapist while also preserving security over their patients data.

Electronic Component Validation [KD]

Data was collected using the electronic components and compared to physical measurements taken with a protractor. (Put in Appendix___ and Section__



(Angles were verified with protractor).

Device Integrity and simulated testing validation [KD]
To increase integrity of the device all mechanical components used were made out of 6061-T6 aluminum which has natural corrosion resistance. All electrical components of the brace were placed in a watertight casing, insulated, and mounted to the brace. All exposed wires were encased in wire casings to prevent them from breaking and to keep them neat so that none of them get caught in the hinge mechanism.

Device Intervention validation [KD]
Lateral movement and hyperextension were checked various times during testing to ensure that the angle restriction was working properly. Hyperextension was prevented by the servo mounting plate which created a mechanical stop at 2° extension which was confirmed using a protractor during testing.

Chapter 7: Regulatory Analysis [JW]

An SE decision making document was filled out to determine the substantial equivalence of the Adaptable Knee Brace compared to currently patented knee braces for similar functions. For this documentation, the Adaptable Knee Brace was compared to the Thuasne Rebel Series L1845. Both products are a device, however since they are both identified by the FDA as joint, knee, and external braces, they are both classified as a class 1 device and therefore are 510k exempt. Although the adaptable knee brace is 510k exempt, it must still undergo some regulatory processes. Since the device is not sterile, the device is GMP exempt besides the general requirements concerning records (820.180) and complaint files (820.198). Additionally, a TPLC product code report is also required. Since the Adaptable Knee Brace is a class 1 device, it is identified as exempt from premarket notification requirements as per 21 CFR Parts 862-892. However, the device must still be registered by the manufacturer using the Device Registration and Listing website.

Chapter 8: Hazard Analysis [JW]

For safety, the device must be able to operate under a low current withdrawal. There are inherent safety risks in a device with external electronics components, so to mitigate the hazards for the device interface with the patient the device should limit current withdrawals to approximately 10mA. 10mA significantly reduces the risk of shock hazards to the patient [13].

The device also must follow several important standards as a mechanical orthopaedic brace with external electrical components which have active influence on motion. The standard includes HCPCS L1844, HCPCS L2795, Social Security Act §1861(s)(9), FDA: Code of Federal Regulations Title 21, 890.3475, and FDA: Code of Federal Regulations Title 21,890.1575.

Knee braces intended for rehabilitation (e.g., HCPCS codes L1832, L1844) typically control the knee flexion-extension angle during the initial healing period after surgery regarding cruciate ligaments or general reconstruction. Rehabilitative braces are typically used for a short duration in the patient's postoperative period to protect the fracture site or surgical repair while range-of-motion, weight-bearing and muscle activity are initiated. The braces allow joint motion in a controlled manner and are required for about 6–12 weeks post-acute injury or surgery to assist in the relevant rehabilitation. They allow adjustment for swelling thus allowing the knee to regain range of motion without pain. The specific rehabilitation brace allows motion and loading to return to a normal state and have been shown to decrease muscle atrophy, maintain cartilage health, and decrease the chance of knee stiffness [19]. There is little published evidence and data in favor of the use of rehabilitative braces over alternative treatment methods, however these braces appear to be accepted clinically and are known to avoid the risks to the knee that are commonly associated with cast immobilization [19].

Angular deformities of the knee joint can lead to knee osteoarthritis. Angular deformities are known to cause overload to the medial compartment and lateral compartment. Knee braces with adjustments for displacement towards and away from the midline (e.g., HCPCS code L1843, L1844, L1845) may be medically necessary for patients who are using rehabilitation for walking and require knee bracing to alleviate pressure on the medial and lateral compartment of the knee [19].

Rehabilitative knee braces targeted towards to elderly must abide by the standard of Social Security Act §1861(s)(9). For medicare to cover medical braces for knee orthosis it must meet the requirements of being a rigid or semi-rigid device and be used for the purpose of supporting a weak or deformed body member or restricting or eliminating movement in a diseased or injured part of the body.

In order for the brace to be viable in the market, it must pass several FDA standards. These regulations set the federal premarket guidelines for being able to market this device in the United States. In this case our device is exempt from the premarket notification process, subpart E of part 807, and is also exempt from the current good manufacturing practices requirement of the quality system regulation in part 820, with the exception of 820.180 and 820.198 which cover records and complaint files respectively. Also, they exempt our device from premarket notification procedures in part E of part 807 and subjects us to the limitations of 890.9. This regulation specifically pertains to taking measurement for ground reaction force which will be a feature in our device.

Chapter 9: Budget & Cost Analysis [JW]

For the initial budget, different categories (i.e. the hinge, support materials, and wires/connectors) were created as preliminary placement holders for this project. Under each of the categories, estimated part prices were added based on websites such as McMaster-Carr, Amazon, and others, to generate an estimated expense list for the project. For this project, each team member was allotted $100, totalling a $400 budget for the team. With the initial price estimates, the total estimated cost for the working prototype was $368.35, which is $31.65 under budget (Table 3).

Table 3: Expected Spending

	$368.35
Remaining	$31.65

Item	Company	Quantity	Part Number	Cost Per Unit	Shipping Cost	Special Handling (Hazards)	Total Cost
Arduino Nano 33 BLE	Amazon	1	ABX00035	$23.00	$0.00	None	$23.00
IMU (BNO055 or BNO085)	Adafruit	1	4754	$19.95	$3.99	None	$23.90
Lithium Ion Battery Pack - 3.7V 6600mAh	Adafruit	1	353	$7.95	$0.00	Battery	$7.95
Wires and Connectors		1		$29.50	$0.00	-	$29.50
Springs		1		$30.00	$0.00	-	$30.00
Support Materials		1		$45.00	$0.00	-	$45.00
Straps		1		$30.00	$0.00	-	$30.00
Fabric + Cushion		1		$30.00	$0.00	-	$30.00
Double Jointed Hinge		1		$20.00	$0.00	-	$20.00
Electric Linear Actuator		1		$120.00	$0.00	-	$120.00
						Total Cost	$368.35

The most expensive components of the prototype, accounting for over half of the expected budget, included the electric linear actuator, the support materials, and the Arduino Nano 33 BLE. Once all of the components were purchased, all remaining funds were designated to be used for replacement parts/materials that may be required for modifications added to the device during the manufacturing and testing phases.

The actual spending for the project was $73.05 under the expected spending and $104.70 under the allotted budget (Table 4).

Table 4: Actual Spending

Item	Company	Quantity	Part Number	Cost Per Unit	Shipping Cost	Special Handling (Hazards)	Total Cost
Arduino Nano 33 BLE	Amazon	1	358-6010602	$22.50	$0.00	None	$22.50
LSM9DS1 IMU sensor	Amazon	1	2129	$14.95	$0.00	None	$14.95
Lithium Ion Battery Pack - 3.7V 6600mAh	Adafruit	1	353	$29.50	$0.00	Battery	$29.50
Wires and Connectors	Amazon	1	N/A	$1.00	$0.00	None	$1.00
Aluminum 6061 1/8" Size: 12"x20"	Metals Depot	2	531878	$42.57	$18.13	None	$101.27
Aluminum 6061 1/4" Size: 5""x12"	Metals Depot	1	F4148	$14.37	$10.48	None	$24.85
Straps	Amazon	1	N/A	$15.07	$0.00	None	$15.07
Neoprene Sleeve	Donjoy	1	N/A	$22.88	$0.00	None	$22.88
Bolts, Washers, and Nuts	Bolt Depot	12	22462	$0.37	$17.25	None	$33.09
		6	22907	$0.28			
		12	24636	$0.25			
		24	24649	$0.14			
		48	23037	$0.07			
High Torque Servo	Amazon	1	N/A	$16.99	$0.00	None	$16.99
Twine	Lowes	1	1289800	$3.93	$0.00	None	$3.93
Washers	Lowes	1	18040	$1.28	$0.00	None	$1.28
Heat Shrink	Lowes	1	707551	$2.28	$0.00	None	$2.28
Mounting tape	Scotch	1	394734	$3.93	$0.00	None	$3.93
Bolts	Lowes	1	62054	$1.28	$0.50	None	$1.78
				Shipping Cost:	$44.36	Total Cost:	$295.30

Material costs were higher than anticipated due to the trial and error that was expected in the manufacturing process of the brace. The supportive material of the brace had to be rolled in order to be manufactured. Since this process has a lot of variability and typically requires multiple attempts to achieve the correct brace shape, four times the required material was purchased to allow for flexibility during the manufacturing process. This caused the material costs to be about $61.12 more than initially anticipated.

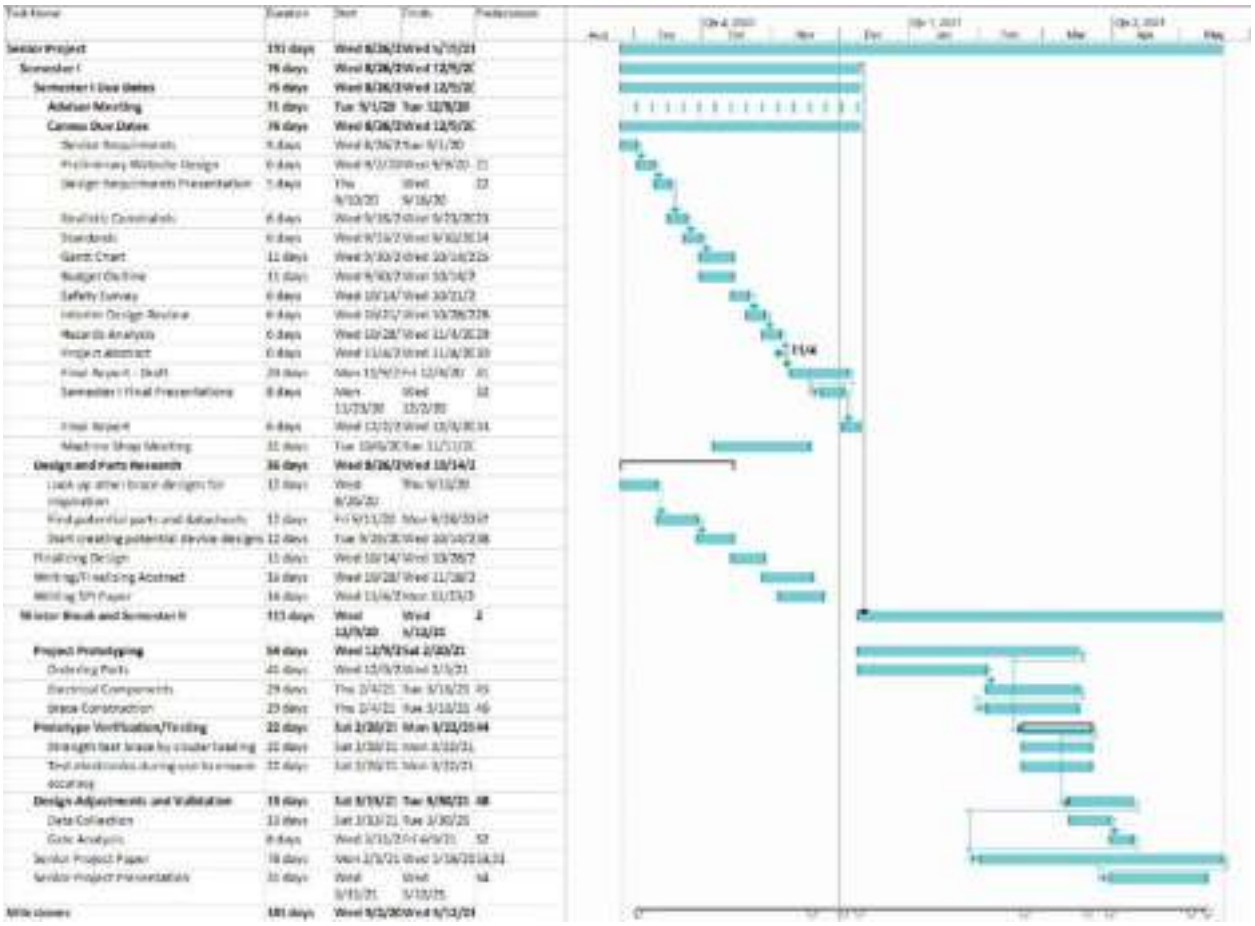
An arduino nano, IMU and high torque servo motor were purchased to replace the raspberry pi, voltage regulator, accelerometer, extra sensors, and the electric linear actuator, which resulted in a savings of about $119.51. This was done mainly to achieve a more cost effective prototype so that additional components of the brace, such as the neoprene sleeve, the twine, the mounting tape, and extra quantities of the support material could be purchased without maxing out the allotted budget.

The lower cost of the project will allow for the future retail cost for the brace to remain low and affordable for most users. As future adjustments are made to the prototype and refinements are also made to simplify the design and create a more practical prototype for marketing, the price may fluctuate. However, since the concept prototype was able to be created with a small budget and spending under $400, this creates a hopeful potential for a low and reasonably affordable brace during future steps in this design process, especially when factors like inhouse manufacturing are considered. In the future large scale manufacturing process of the device, bulk parts and materials can be ordered, which can result in price reductions as large as 20-30% per device. This price reduction allows marketing to charge a low cost for the device while still maintaining a high return value for the project.

Chapter 10: Schedule Analysis [JW]

The project timeline aligned with the initial Gantt chart throughout most of the project, however, the actual timeline was about 2 weeks late compared to the initial timeline. This 2 week shift caused the project to only have about 2 weeks to execute verification and validation testing, rather than having the planned full month for execution. However, 2 weeks proved to be sufficient in generating and analyzing the data from testing, so this delay did not cause any major shifts in the project timeline, i.e., all deadlines and milestones were met accordingly. See Table 5 below for the project Gantt Chart.

Table 5: Gantt Chart



Although the timeline was met with a relatively high degree of accuracy, in the future, the team's ability to better meet the schedule could be achieved by having more working team meetings (rather than just overview/future step meetings to assign and review work) to stay on top of assignments in a more orderly fashion. This will allow the group to address any confusion or issues that occur with assignments immediately, rather than waiting until the next weekly team meeting to discuss it.

Chapter 11: Conclusion [JW]

Most of the currently marketed knee braces are designed to assist the patient using supportive and stabilizing techniques, however, they provide limited assistance to the patient in actually executing the gait cycle motions for gait rehabilitation. The Adaptable Knee Brace is a viable option for a rehabilitative knee brace that assists patients throughout their gait cycle by potentially improving the patient's knee range of motion as well as by correcting the patient's knee angles throughout the rehabilitative cycle. The design incorporated a modified double hinge that offered a controlled monitoring of the angle of the knee throughout the gait motion to assist patients who have a limited degree of knee motion. Although a larger budget is needed to make the device fully adaptable, the verification and validation activities have shown large potential for progressing with this design for the intended use. With more research and development testing and a larger budget, a prototype that is oriented more towards a final product could be created that fully meets all of the design inputs.

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Appendices

Appendix Number	Title
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3	Realistic Constraints
4	Drawing Sheets
5	Codes
6	Material List
7	Hazard Analysis
8	Verification Protocols & Completion Reports
9	Validation Protocol & Completion Report
10	Engineering Standards & Specs
11	Life-Long Learning Essay
12	Ethical Considerations
13	Meeting Minutes

Appendix 1: Team Biographies

Avneet Chawla

I am a biomedical engineer with a background in neural engineering. Outside of the normal curriculum I completed 2 years of research in Dr. Xuefeng Wei's neural engineering lab. I completed projects creating randomized arrays of neurons and stimulated them at different points while modeling the receiving point current and graphing them as andromically evoked population spikes. I also created and used solidworks models of electrodes with different shaped electrodes and varied the parameters of stimulation with novel algorithms for deep brain stimulation. I created 3D visual designs for the stimulation parameters of the novel recessed curvature electrode design used in my research lab for experimentation. After research at TCNJ with respect to modeling DBS I will likely take the skills I have accrued and apply them to future jobs and research endeavors.

After graduation I plan to take a gap year to conduct research, volunteer, and shadow physicians. I will take at least a year to get myself acquainted with the medical fields and hopefully pursue a career in medicine.

Justina Walck

I am a Biomedical Engineer with a strong background in Mechanical Engineering. Outside of my BME education, I worked for about 3.5 years in a machine shop: (1) learning how to properly design parts for manufacturing with realistic tolerances based on different machinery, (2) using heavy duty machinery such as the water jet machine, metal working lathes, and milling machines to machine various parts for different senior project and research groups, (3) consulting with various individuals on material choices for projects and the best manufacturing approaches to take to meet those projects, and (4) troubleshooting issues that came up with machinery malfunctions, designs not properly translating into the machinery, and design alterations.

After working in the machine shop, I had the opportunity to work full-time during my senior year at Johnson & Johnson ETHICON in the R&D wound closure performance evaluation department. During this role, I had the chance to work with various departments across the company, worked on developing new and innovative wound closure products, and was exposed to lifecycle management documentation, such as: strategies, IQ/OQ/PQ protocols, work instructions, test methods, and reports. Gaining the experience of the design control process from this senior project allowed me to apply what I learned directly to my position in industry, which was a very unique opportunity to experience.

Post graduation, my career goals involve building my technical background in engineering for the next few years before taking on the challenge of becoming the director of a medical device department one day.

Karl Devoe

I am a Biomedical Engineering major with a strong background in Electrical Engineering. Outside my major I worked for 2 years as a lab assistant in Armstrong hall. During this I helped keep the electronics labs stocked with supplies and helped ensure all equipment was in working order. After graduation I intend on going into industry before deciding if I would like to pursue further education. My career goal is to be able to use my education in Biomedical engineering and my strong background in Electrical engineering to design and develop advanced limb prosthetics which integrate into the patents existing biology.

Alex Carideo

I am an Electrical Engineering major with a background in embedded systems and robotics. I have worked as a teachers assistant in ENG-095 Introduction to engineering class, and interned at Princeton Plasma Physics Laboratory, HDR Inc, and Linearizer Technology Inc.

At Princeton Plasma Physics Laboratory I worked with 3D printers and learned about 3D modeling and design which has helped me with various design problems and will continue to aid me.

At HDR, an architectural and engineering company, I learned about 3D modeling software for design and documentation of building projects based on architectural building code. This specific knowledge and learning experience has given an interesting perspective on the electrical engineering industry in relation to building specific design and development which will help me if I decide to enter that field of engineering.

At Linearizer Technology I analyzed properties of RF electronic devices over various temperatures and frequencies. This gave me an interesting perspective on RF and Microwave electrical and communication engineering that will also be helpful if I chose to go into that specific field of engineering.

After graduation I intend on going into industry before deciding if I would like to pursue further education. My career goal is to be able to use my education in electrical engineering to design and develop electrical devices. With my wide range of work experience I have gained an interesting perspective on the industry which will help me be well prepared for my future career.

Appendix 2: Design Matrix

Table 1: Design Matrix for the Brace

	Design Matrix: Brace Design			
	Mobility	**Stability**	**Restriction**	**Expense**
Brace Alone	More mobility due to less constriction on the leg	Reduced stability due to less keeping it on	Less restrictive due to having no compression sleeve	Less expensive due to not needing the sleeve
Brace with compression sleeve	Less mobility due to the sleeve constricting the leg	Increased stability due to having the compressive sleeve helping to keep it in place	Has a possibility to restrict motion	More expensive since it has the cost of the compressive sleeve on top of the cost of the brace

Table 2: Design Matrix for the Hinge System

	Design Matrix: Hinge Design			
	Complexity	**Restriction**	**Range of Motion**	**Cost**
Single Hinge (Free Joint)	The least complex of our potential designs which consists of a simple hinge and spring system	Springs are used to restrict and assist motions	Limited, only rotational	Cheapest design
Single HInge (Mechanically Restricted)	Slightly more complex consisting of a hinge with a mechanical resistance system	Mechanical methods such as metallic bars restrict and assist motions	Limited, only rotational	Mid range expense
Double Hinge	The most complex design consisting of two hinges which allow for a great range of motion	Metallic bars and or spring restrict and assist motions	Accounts for both rotational and vertical motion	Most expensive design option

Table 3: Design Matrix for the Microcontroller

	Design Matrix: Microcontroller								
	Price	**Memory**	**Clock Speed**	**Multitasking**	**Voltage**	**Flash**	**USB**	**Operating System**	**Integrated IMU**
Raspberry PI Model B	$35.00	512MB	700 MHz	Yes	5V, This voltage is within a safe range which would not cause harm is something were to go wrong	SD Card (2-16GB)	Two	Linux distributions	None
Arduino UNO	$30.00	2KB	16 MHz, Not the best option since we plan on our device needing a high frequency	No, Not good since we are planning on having multiple inputs running at the same time	7-12V, Neither good nor bad, higher then we would like but low enough not to change anything	32KB,Storage is very low for our device to be ran for any length of time	One	None	None
Arduino Nano 33 BLE	$20.20	256KB	64 MHz	No, Not good since we are planning on having multiple inputs running at the same time	3.3-21V, This voltage is within the safe range which would not cause harm	1MB, Low memory but could be made to work	One	None	LSM9DS1

Table 4: Design Matrix for the Combined IMU

	Design Matrix: Combined IMU						
	Absolute Orientation	**Velocity Vector**	**Acceleration Vector**	**Gravity Vector**	**Temperance**	**Power Input**	**Price**
BNO055	3-axis at 100Hz	3-axis (in rad/s) at 100Hz	3-axis (gravity+ linear motion in m/s^2) at 100Hz	3-axis (minus any movement in m/s^2) at 100Hz	Ambient temperature at 1Hz	2.4-3.6V	$19.95
BNO085	3-axis at 100Hz	3-axis (in rad/s) at 100Hz	3-axis (gravity+ linear motion in m/s^2) at 100Hz	3-axis (minus any movement in m/s^2) at 100Hz	Ambient temperature at 1Hz	2.4-3.6V	$19.95
LSM6DS33	3-axis at 104Hz	3-axis at 104Hz	3-axis at 104Hz	3-axis at 104Hz	None	Max 4.8V	$11.95

Table 5: Design Matrix for the Design Solutions

	Design Matrix: Design Solutions							
	Cost	**Complexity**	**Practicality**	**Efficiency**	**Weight**	**Battery Life**	**Material**	**Performance**
Design 1: Brace Only, Single Hinge (free joint), Microcontroller and IMU	Least cost overall	Lest complex due to the simple brace and hinge design being used	This device would restrict vertical movement and not provide the proper form of resistance	This design is the least able to fulfill our purpose	Weights the least of designs	Since all designs have the same electronics the battery life for all devices will be the same	This would require the least materials but the spring is the worst of the three resistance systems	This would perform the least effective in providing assistance for gate rehabilitation
Design 2: Brace & Compression Sleeve, Single hinge (mechanically Restricted), Microcontroller and IMU	Mid range cost	Slightly more complex since the brace also includes the compressive sleeve and mechanically resistive hinge design	This design would be okay for our purpose but would restrict vertical movement	This design will fulfill our purpose but restrict vertical movement	Weights slightly more then the free joint design due to the mechanically restrictive hinge design		This system is better since it has the mechanical resistance which is better than a spring	This would be adequate for gate rehabilitation but would restrict movement to a degree
Design 3: Brace & Compression Sleeve, Double hinge system, Electric Linear Actuator, Microcontroller and IMU	Most expensive	The most complex design since it has both the compressive sleeve and the double hinge system	This design would be the most applicable to what we want to do and allow the user to have the best range of motion	This device would be the most efficient for the user in both resistance and range of motion	The heaviest of the three since it has the double joint system which is heavier then the single joint designs		This would be the best design material wise even though it would take the most materials since it would allow for the most natural gait posture	This would be the best option for gate rehabilitation since it would not provide any vertical range of motion restriction

Appendix 3: Realistic Constraints

Design Requirement	Realistic Constraint	Justification
The device hinge system must be able to provide minor vertical motion (motion due to impact) and rotational motion (knee bending and flexing).	Manufacturability	The hinge system must be able to be manufactured repeatedly with minimal (+/- 0.05in) variance in the part (1). Manufacturability of a device with multiple hinges in a design requires a much greater precision as well as the specific tolerances for each bearing, and if tolerances are exceeded then the lifespan of the device significantly decreases.
The device must provide maximal support during the stage of the maximal vertical force in the gait cycle.	None	While this requirement does not fall into any specific category for engineering constraints it is still necessary for our device to be able to support the maximum working load which in this case would be three times the patient's body weight during strenuous activities (2).
The electrical components must operate with a very low latency.	Economic Manufacturability	Decreasing the latency of a sensory system will significantly increase the cost and manufacturability of the device. The device must be developed using small, low cost sensors with a reliable latency factor on the order of milliseconds (3).
The electrical components must operate with a high frequency of data collection at the cost of power consumption.	Economic Manufacturability	Increasing the frequency of data collection and battery capacity of the system will significantly increase the cost and manufacturability of the device (4). The device must be developed using sufficient battery capacity under the constraints for it to be a low cost and reliable device in the application of gait analysis.
The electrical components must operate with a high degree of accuracy.	Economic Manufacturability	Increasing the accuracy of the system will significantly increase the cost and manufacturability of the device. The device must be developed using a high degree of accuracy to be reliable in the application of gait analysis (5).
The device must be able to support the weight of the average person over the age of 65 (both male and female).	Global Societal	Average weights vary across different countries, so the maximum weight must be considered for the most obese country (6). Weight varies across different areas and is typically a societal constraint. In several areas

		across the US, societal norms vary from heavy exercisers to obsese populations so the device must be able to handle such deviations as well as the averages.
The device must be partially environmentally friendly and able to be partially recyclable.	Environmental Political	Devices must use at least 1/5 environmentally friendly material to allow for recycling of the device. Political constraints may occur depending on who controls the office and the majority of congress. Republicans tend to have less environmental restricting policies while democrats tend to have more restrictions. Local elections may also influence the types of recyclable materials in certain districts (7).
The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993.	Health and Safety	The device must follow the guidelines listed in accordance with current biocompatibility laws enforced by the FDA (8)
The device must be reasonably inexpensive to purchase so the user can afford the device. (less than $500)	Economic	The targeted patient of the device is above the age of 65 and is likely covered under medicaid (9). If however this device is not deemed under the "medically necessary" guidelines then the out of pocket costs should be affordable for a fixed income retired individual.
The device must last for at least 10 years	Sustainability Economic	Current knee braces which treat osteoarthritis typically must prolong the patient's ability to walk without the need of surgery in the future (10). By prolonging the period the brace is not recycled or thrown out reduces short term environmental damage. By increasing the longevity of the device, the cost for treatment for osteoarthritis to the user significantly decreases.

Appendix 4: Drawing Sheets

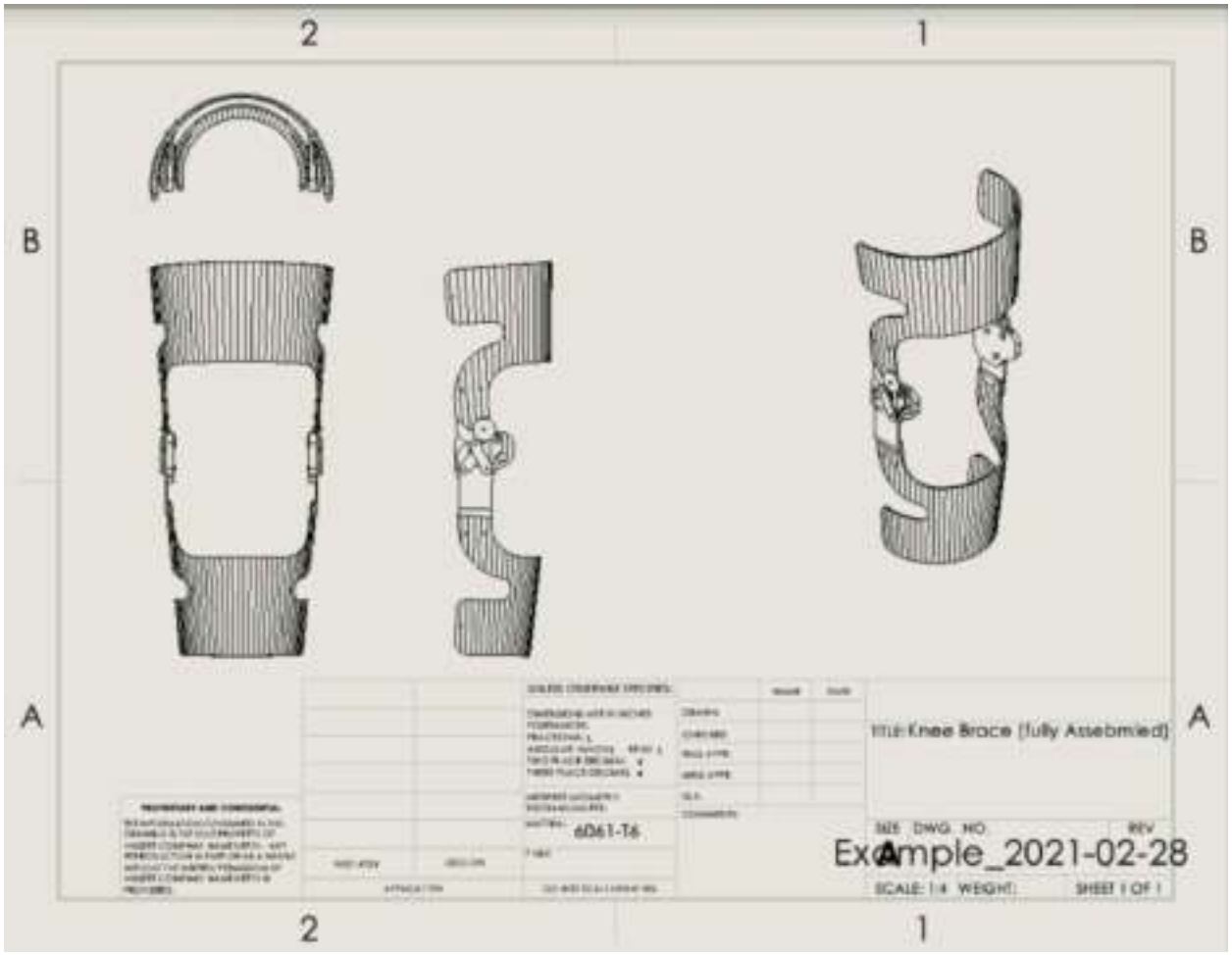


Figure 1. Knee Brace Assembly

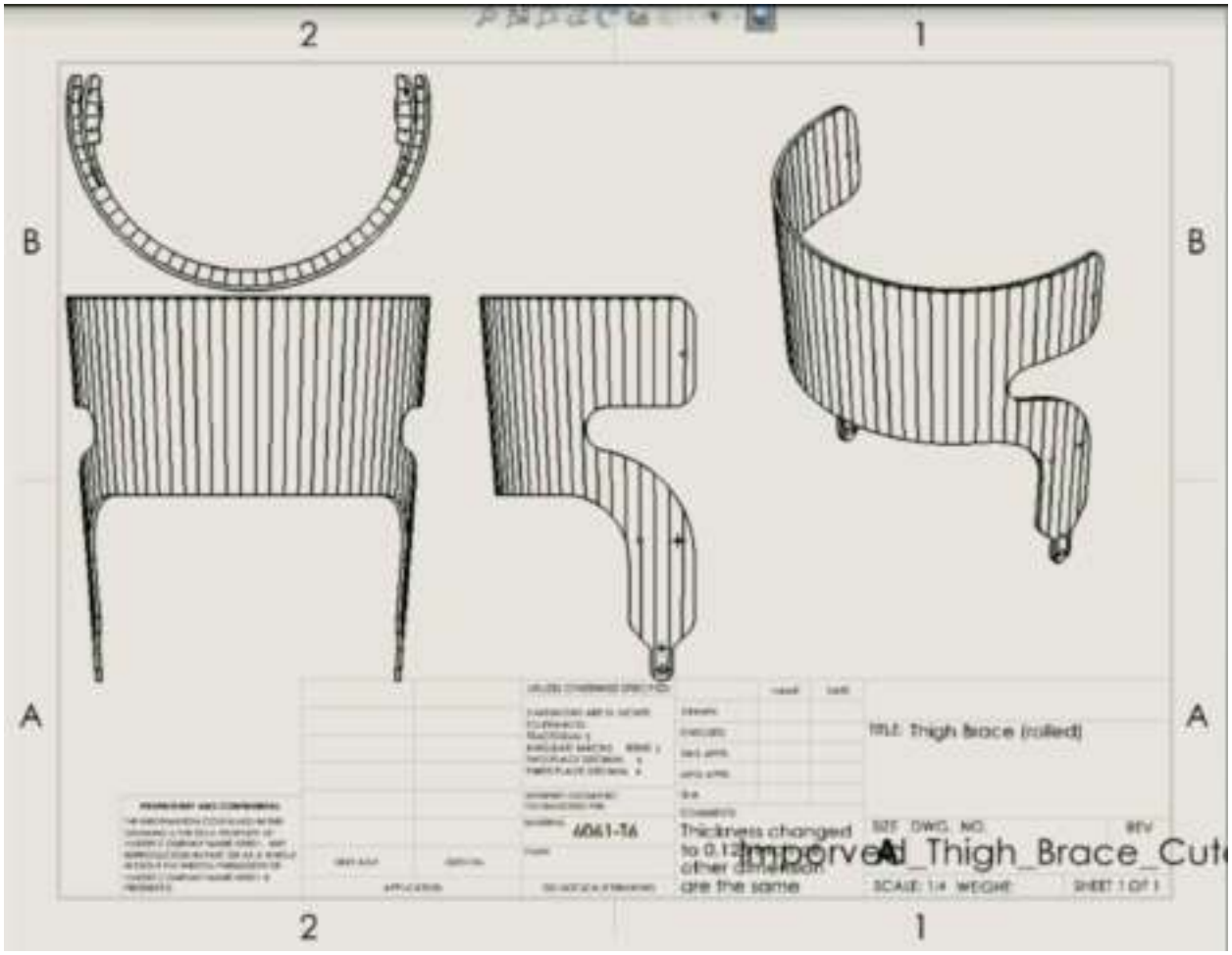


Figure 2. Thigh Brace Component

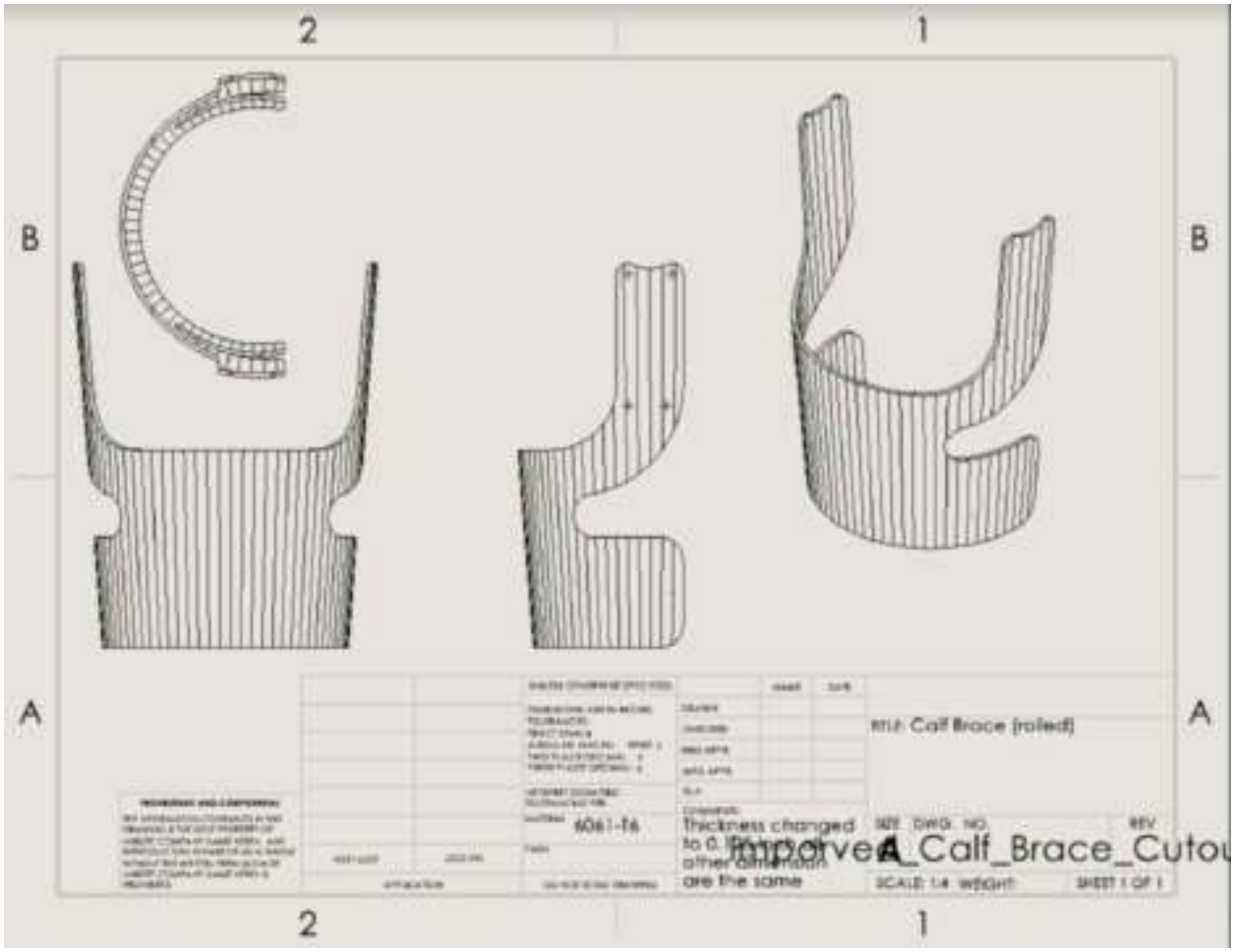


Figure 3. Calf Brace Component

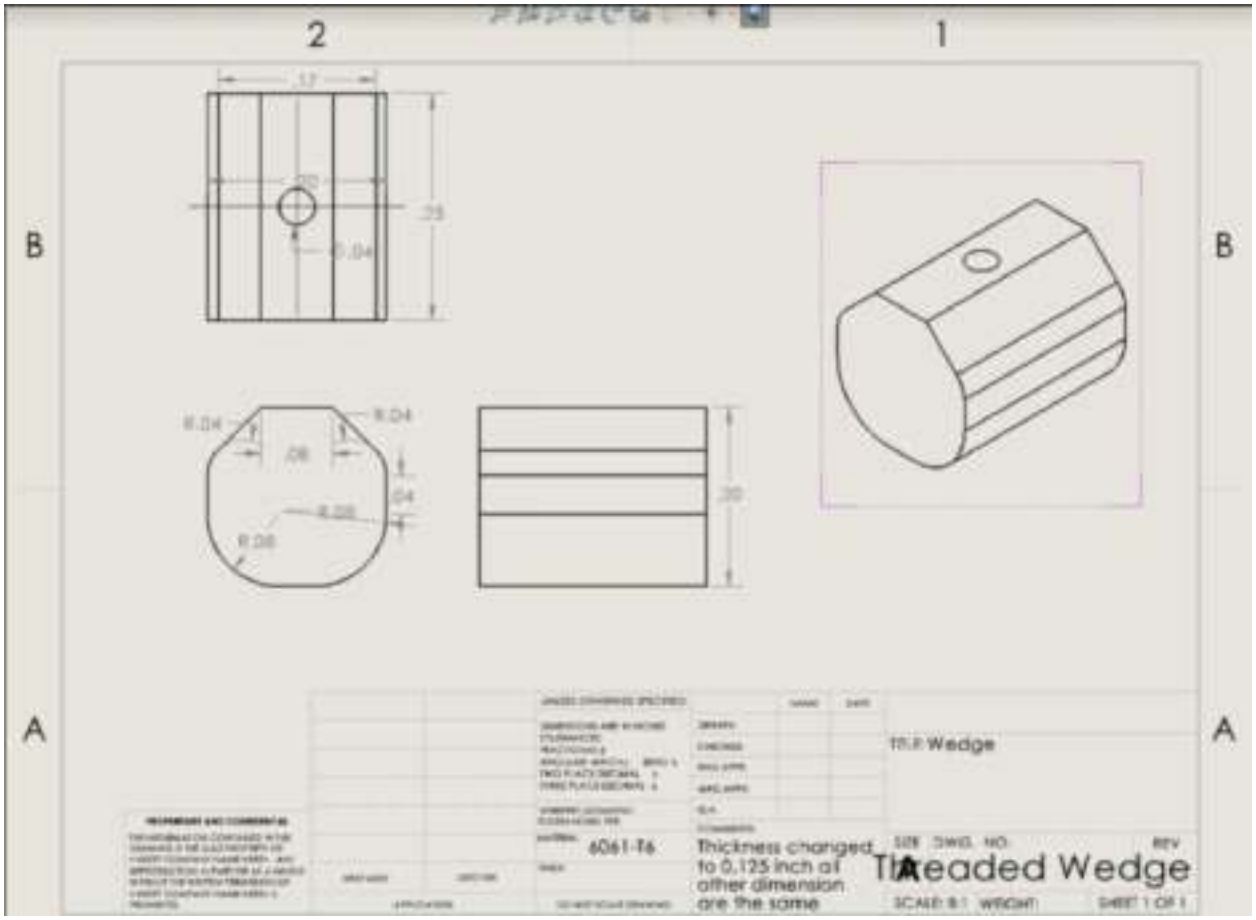


Figure 4. Hinge Wedge Component

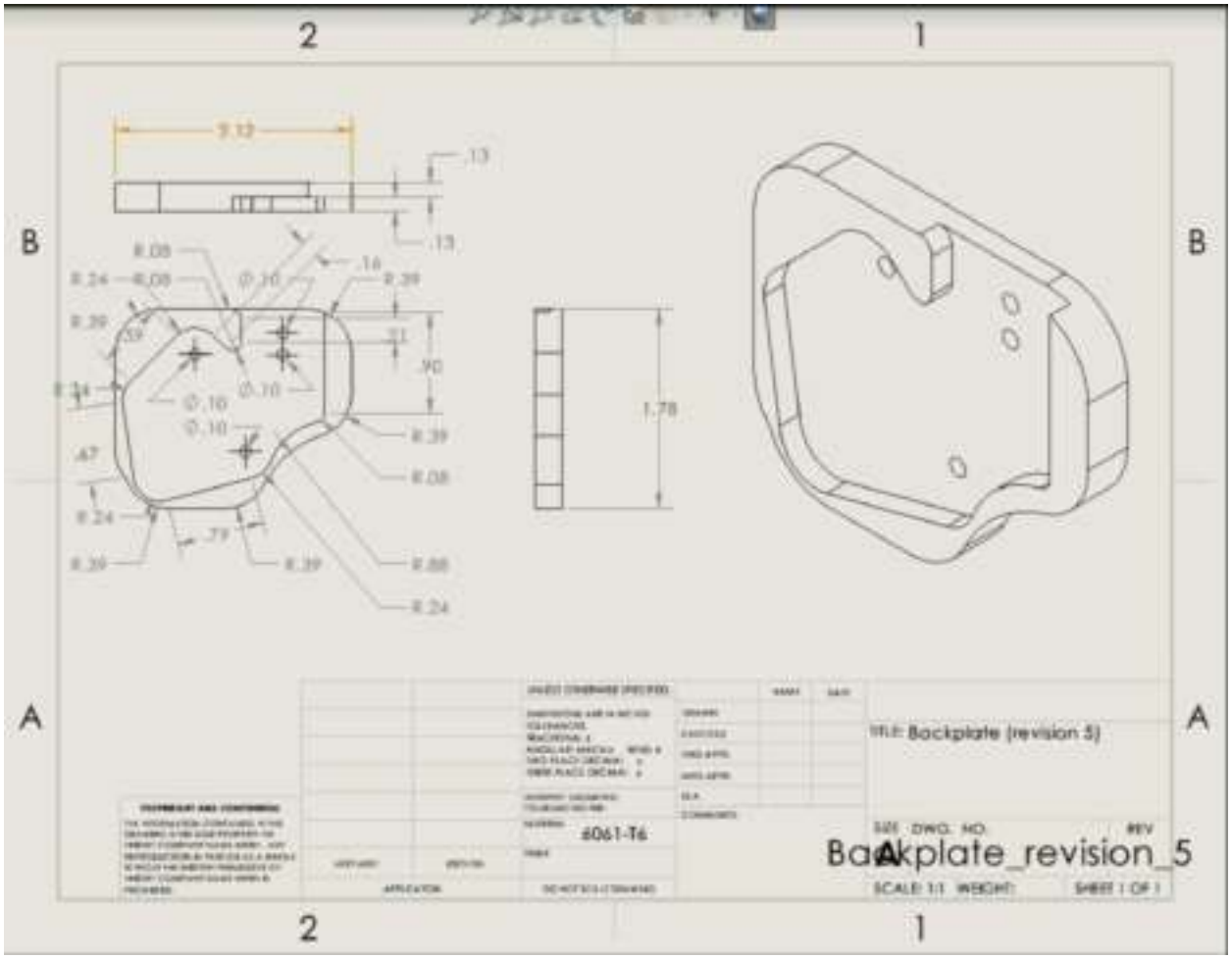


Figure 5. Hinge Backplate Component

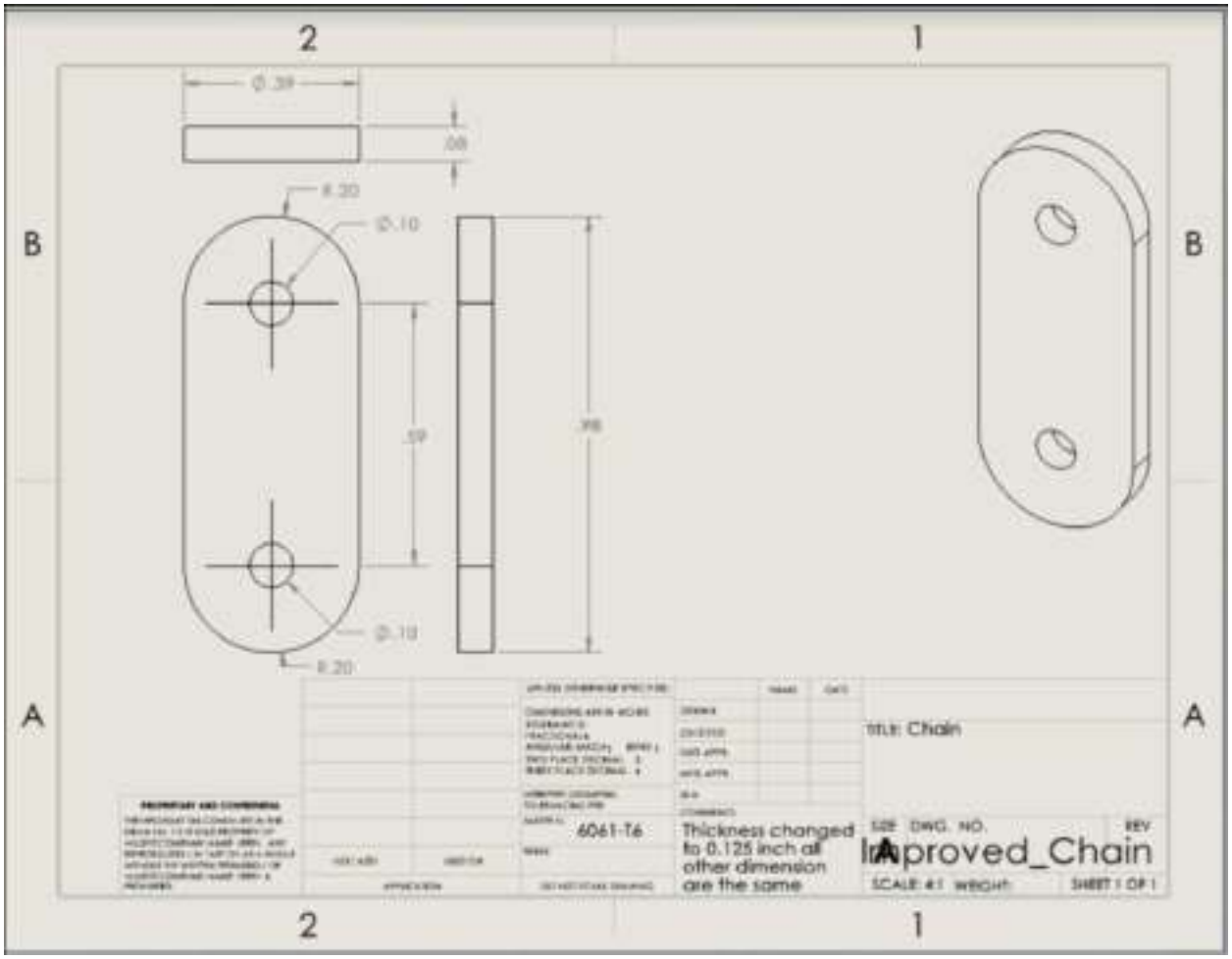


Figure 6. Hinge Chain Component

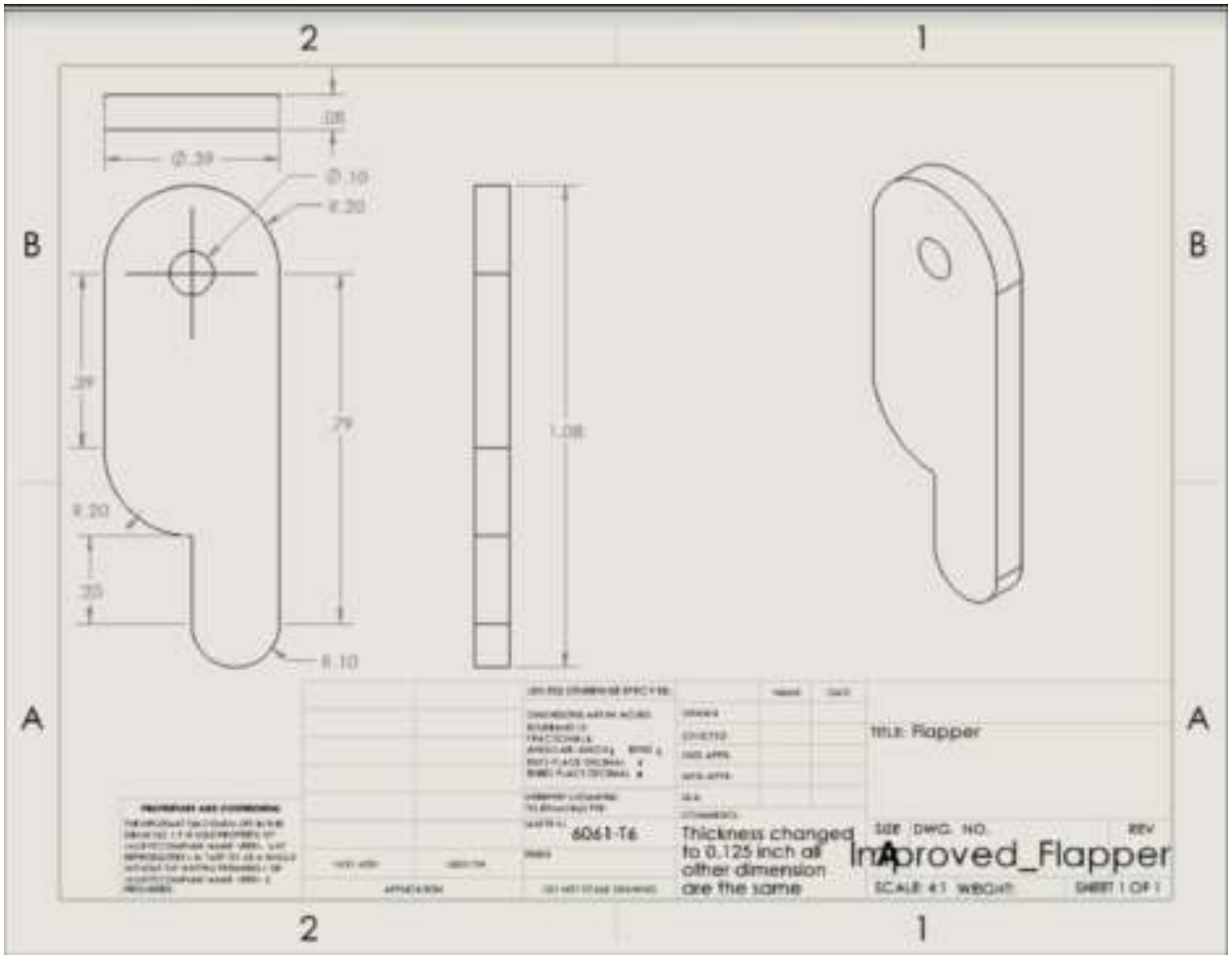


Figure 7. Hinge Flapper Component

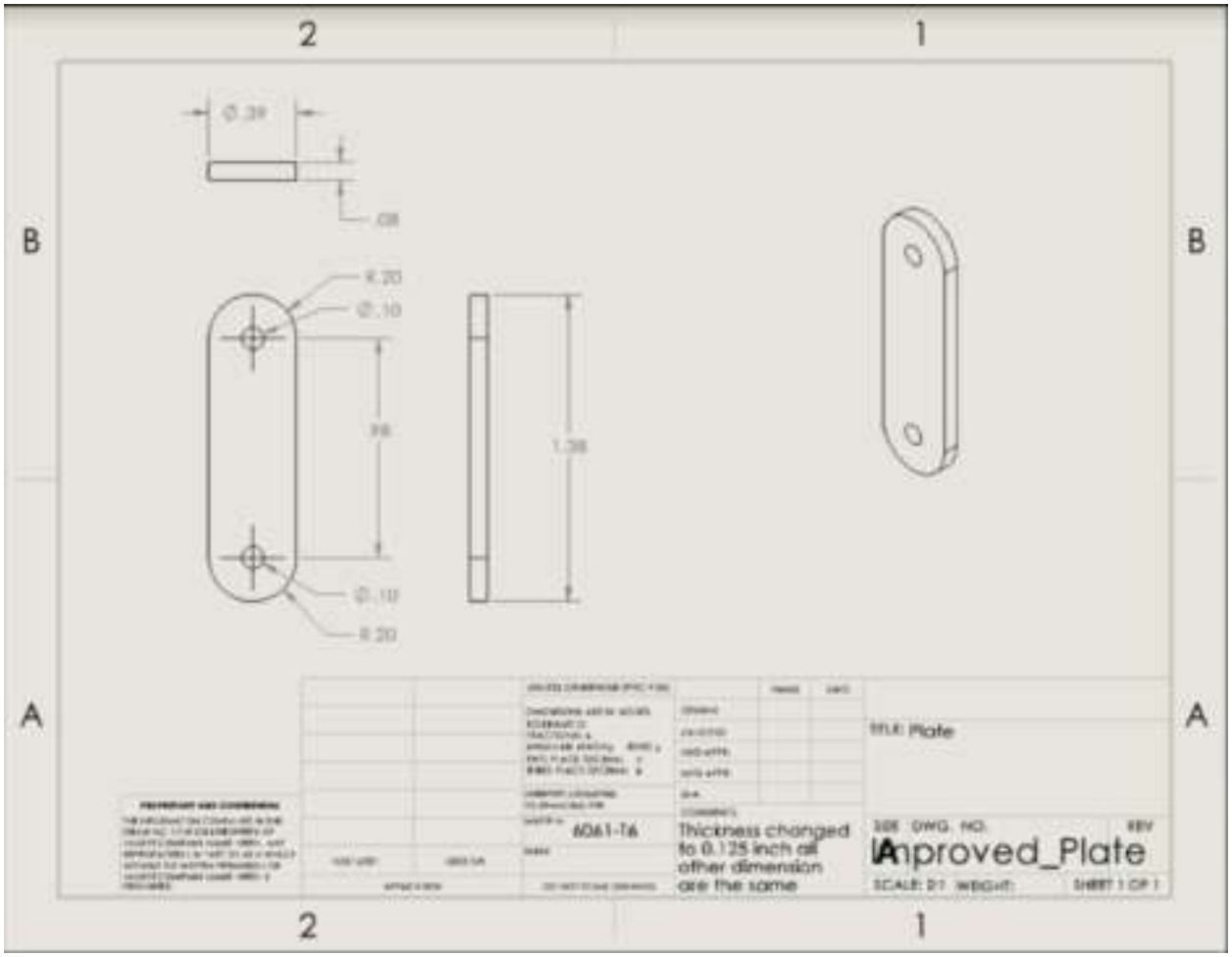


Figure 8. Hinge Plate Component

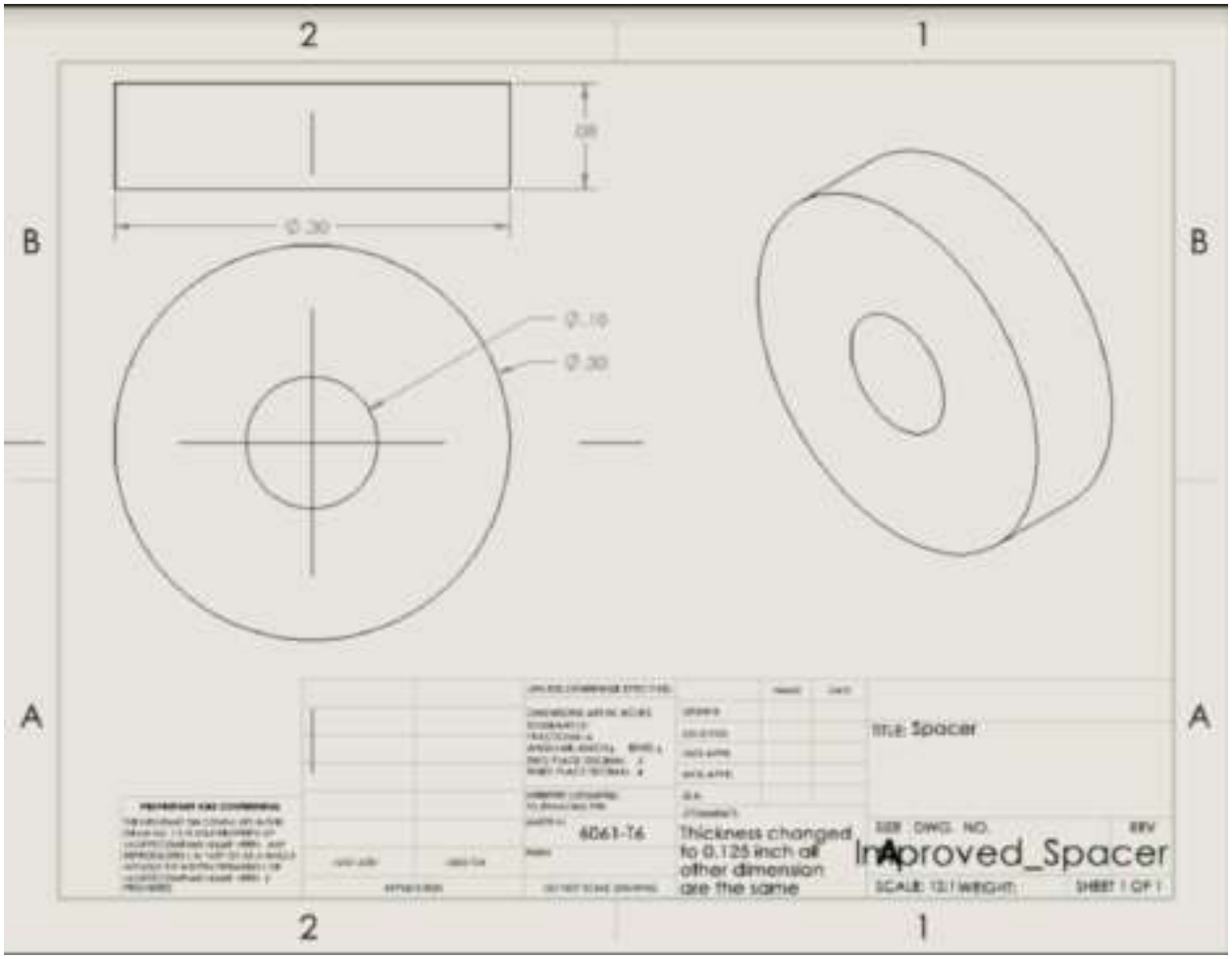


Figure 9. Hinge Spacer Component

Appendix 5: Codes

Low Latency Testing Accelerometer Code:

```
/*
  Arduino LSM9DS1 - Simple Accelerometer
  Extended with library V2.0 function calls

  This example reads the acceleration values from the LSM9DS1
  sensor and continuously prints them to the Serial Monitor
  or Serial Plotter.

  The circuit:
  - Arduino Nano 33 BLE (Sense)
  - or Arduino Uno connected to LSM9DS1 breakout board

  created 10 Jul 2019
  by Riccardo Rizzo

  Modified by Femme Verbeek 10 jul 2020

  This example code is in the public domain.
*/

#include <Arduino_LSM9DS1.h>
boolean viewInSerialPlotter=true;      //true optimises for serial plotter, false for serial
monitor

void setup()
{  Serial.begin(115200);
   while (!Serial);

   if (!IMU.begin())
   { Serial.println("Failed to initialize IMU!");
     while (1);
   }
/*******************    For an improved accuracy run the DIY_Calibration_Accelerometer sketch
first.     ****************
*******************         Copy/Replace the lines below by the code output of the program
****************/
   IMU.setAccelFS(3);
   IMU.setAccelODR(5);           //
   IMU.setAccelOffset(0, 0, 0);  //   uncalibrated
   IMU.setAccelSlope (1, 1, 1);  //   uncalibrated
/*****************************************************************************************
************************************
*******  FS  Full Scale         range 0:±2g | 1:±24g | 2: ±4g | 3: ±8g  (default=2)
******
*******  ODR Output Data Rate   range 0:off | 1:10Hz | 2:50Hz | 3:119Hz | 4:238Hz | 5:476Hz,
(default=3)(not working 6:952Hz) ******
*****************************************************************************************
************************************/
   IMU.accelUnit=  GRAVITY;    // or  METERPERSECOND2

   if (!viewInSerialPlotter)
   {  Serial.println("Gyroscope in degrees/second \n");
      Serial.print("Accelerometer Full Scale = ±");
      Serial.print(IMU.getAccelFS());
      Serial.println ("g");
      Serial.print("Accelerometer sample rate = ");
      Serial.print(IMU.getAccelODR());        // alias  AccelerationSampleRate());
      Serial.println(" Hz \n");
      delay(4000);
   }
   Serial.println(" X \t Y \t Z ");
}

void loop() {
  float x, y, z;
```

```
  if (IMU.accelAvailable())                  // alias IMU.accelerationAvailable in library
version 1.01
  {  IMU.readAccel(x, y, z);                 // alias IMU.readAcceleration  in library
version 1.01

     Serial.print(x);
     Serial.print('\t');
     Serial.print(y);
     Serial.print('\t');
     Serial.println(z);
  }
}
```

Low Latency Testing Gyroscope Code:

```
/*
  Arduino LSM9DS1 - Simple Gyroscope
  Extended with library V2.0 function calls

  This example reads the gyroscope values from the LSM9DS1
  sensor and continuously prints them to the Serial Monitor
  or Serial Plotter.

  The circuit:
  - Arduino Nano 33 BLE Sense
  - or Arduino Uno connected to LSM9DS1 breakout board

  created 10 Jul 2019
  by Riccardo Rizzo

  Modified by Femme Verbeek 14 jul 2020

  This example code is in the public domain.
*/

#include <Arduino_LSM9DS1.h>
boolean viewInSerialPlotter=false;      // true optimises for serial plotter, false for serial
monitor

void setup() {
  Serial.begin(115200);
  while (!Serial);

  if (!IMU.begin())
  { Serial.println("Failed to initialize IMU!");
    while (1);
  }
/*******   The gyroscope needs to be calibrated. Offset controls drift and Slope scales the
measured rotation angle  *********
*****************   Copy/Replace the lines below by the output of the
DIY_Calibration_Gyroscope sketch   ********************/
   IMU.setAccelFS(3);
   IMU.setAccelODR(3);
   IMU.setGyroOffset (0, 0, 0);  // = uncalibrated
   IMU.setGyroSlope  (1, 1, 1);  // = uncalibrated
/*****************************************************************************************
*******************************
*********  FS  Full Scale       setting 0: ±245°/s | 1: ±500°/s | 2: ±1000°/s | 3: ±2000°/s
***************************
*********  ODR Output Data Rate setting 0:off | 1:10Hz | 2:50Hz | 3:119Hz | 4:238Hz | 5:476Hz,
(not working 6:952Hz)   *******
*****************************************************************************************
*******************************/
   IMU.gyroUnit= DEGREEPERSECOND;  //   DEGREEPERSECOND  RADIANSPERSECOND  REVSPERMINUTE
REVSPERSECOND
   if (!viewInSerialPlotter)
   {  Serial.println("Gyroscope in degrees/second \n");
      Serial.print("Gyroscope Full Scale = ±");
      Serial.print(IMU.getGyroFS());
      Serial.println ("°/s");
      Serial.print("Gyroscope sample rate = ");
```

```
      Serial.print(IMU.getGyroODR());        //alias  IMU.gyroscopeSampleRate());
      Serial.println(" Hz");
      delay(4000);
   }
   Serial.println("X \t Y \t Z");
}

void loop() {
  float x, y, z;

  if (IMU.gyroAvailable())    // alias IMU.gyroscopeAvailable
  {
     IMU.readGyro(x, y, z);   // alias IMU.readGyroscope
     Serial.print(x);
     Serial.print('\t');
     Serial.print(y);
     Serial.print('\t');
     Serial.println(z);
  }
}
```

Low Latency Testing Magnetometer Code:

```
/*
  Arduino LSM9DS1 - Simple Magnetometer
  Extended with library V2.0 function calls

  This example reads the magnetic field values from the LSM9DS1
  sensor and continuously prints them to the Serial Monitor
  or Serial Plotter.

  The circuit:
  - Arduino Nano 33 BLE Sense
  - or Arduino connected to LSM9DS1 breakout board

  created 10 Jul 2019
  by Riccardo Rizzo

  Modified by Femme Verbeek
  10 July 2020

  This example code is in the public domain.
*/

#include <Arduino_LSM9DS1.h>
boolean viewInSerialPlotter=true;      // true optimises for serial plotter, false for serial
monitor

void setup()
{ Serial.begin(115200);
  while (!Serial);

  if (!IMU.begin())
  {
    Serial.println("Failed to initialize IMU!");
    while (1);
  }

/*****************   For a proper functioning of the magnetometer it needs to be calibrated
*******************
*****************   Replace the lines below by the output of the DIY_Calibration_Magnetometer
sketch   *******************/
   IMU.setMagnetFS(0);
   IMU.setMagnetODR(8);
   IMU.setMagnetOffset(0,0,0);  //  uncalibrated
   IMU.setMagnetSlope (1,1,1);  //  uncalibrated
/*****************************************************************************************
*******************************
****  FS  Full Scale        range (0=±400 | 1=±800 | 2=±1200 | 3=±1600  (µT)
*****
```

```
****  ODR Output Data Rate  range (6,7,8)=(40,80,400)Hz | not available on all chips (0..5):
(0.625,1.25,2.5,5.0,10,20)Hz *****
*********************************************************************************************
*******************************/
   IMU.magnetUnit = MICROTESLA;  //   GAUSS   MICROTESLA   NANOTESLA

   if (!viewInSerialPlotter)
   {  Serial.println("Magnetic Field in µT");
      Serial.print("Magnetometer Full Scale = ±");
      Serial.print(IMU.getMagnetFS());
      Serial.println ("µT");
      Serial.print("Magnetic field sample rate = ");
      Serial.print(IMU.getMagnetODR());        // alias IMU.magneticFieldSampleRate in library
version 1.01
      Serial.println(" Hz");
      delay(4000);
   }
   Serial.println("X \t Y\t Z");
}

void loop() {
  float x, y, z;

  if (IMU.magnetAvailable())                   // alias IMU.magneticFieldAvailable in library
version 1.01
  { IMU.readMagnet(x, y, z);                   // alias IMU.readMagneticField in library
version 1.01

    Serial.print(x);
    Serial.print('\t');
    Serial.print(y);
    Serial.print('\t');
    Serial.println(z);
  }
}
```

Servo Testing Code:

```
 /*============================================================
  Author's: Alex Carideo
  Modified By: -
  Date:
  Course:
  File:  servoTest.ino
  Rev #: 1.0
  Description:  This program tests the servo,
==============================================================*/

// Global Variables
int servoPin = A0;      // defines servo signal pin, power snd ground
                      //
int onboardLEDPin = 13;  // defines the pin of the onboard LED
int servoValue;
void setup()
{
      // put your setup code here, to run once:
      Serial.begin(9600);           // Serial address
      pinMode(servoPin, OUTPUT);    // Sets the servo pin as an output
      pinMode(onboardLEDPin, OUTPUT); // Sets the onboard LED pin as an output
      // while(!Serial);     // wait to execute loop program until the serial monitor is
opened
     // blinkNum(3);                  // call function blinkNum with numBlinks parameter

}

void loop()
{
      // put your main code here, to run repeatedly:
```

```
      servoConstant();  // Call function servoConstant to hold the position of the servo
static
      //servoContinous(); // Call function servoContinous to continuously change between all
servo positions
}

//For testing individual positions
void servoConstant()
{
     int x = 0;  // Initialize x to zero
    while (x == 0)
    {
          digitalWrite(servoPin, HIGH);   // enable servo
          delayMicroseconds(400);    // Set servo position

          digitalWrite(servoPin, LOW);  // disable servo
          delay(20);                   // REQUIRED delay to give the servo time to move

//          delay(1000);
//
//          digitalWrite(servoPin, HIGH);   // enable servo
//          delayMicroseconds(700);    // Set servo position
//
//          digitalWrite(servoPin, LOW);  // disable servo
//          delay(20);                   // REQUIRED delay to give the servo time to move
//
//          delay(1000);
//
//          digitalWrite(servoPin, HIGH);   // enable servo
//          delayMicroseconds(900);    // Set servo position
//
//          digitalWrite(servoPin, LOW);  // disable servo
//          delay(20);                   // REQUIRED delay to give the servo time to move
//
//          delay (1000);

          x = x + 1;
    }
}

// For testing a range of positions
void servoContinous()
{
      for (int j = 0; j <= 3000; j+= 10) // Step servo by 10 through pulse widths 500 to 2200
      {
          servoValue = analogRead(servoPin);
          Serial.println(servoValue);
          digitalWrite(servoPin, HIGH);   // enable servo
          delayMicroseconds(j);         // Set servo position
          digitalWrite(servoPin, LOW);  // disable servo
          delay(20);                    // REQUIRED delay to give the servo time to move
      }
}

//blinkNum: Used as an onboard indication that thet code has uploaded
void blinkNum(int numBlinks)  //Blinks the onboard LED (numBlinks) (3) times
{
      for (int i = 0; i < numBlinks; i++) // blinks led numBlinks times by incrementing i
      {
          digitalWrite(onboardLEDPin, HIGH);  //enables the onboardLED, turning it on
          delay(100);                        //delay before turning LED off
          digitalWrite(onboardLEDPin, LOW);   //disables the onboardLED, turning it off
          delay(50);                //delay before turning LED on again, blinking the LED
      }
}
```

Accelerometer Calibration:

```
/* DIY calibration program for the LSM9DS1 chip
 *
 * Follow the instructions on the screen how to do calibration measurements.
```

```
 * See instruction video https://youtu.be/BLvYFXoP33o
 * No special tools or setups are needed, however it is handy if the board with the LSM9DS1
chip is fitted inside
 * a non-metalic rectangular box.
 * The Full Scale (FS)and Output DATA Rate (ODR) settings as well as offset and slope factors
 * are displayed on screen as code that can be copy/pasted directly into a sketch.
 * Each new instance of the chip will require it's own unique set of calibration factors.
 * It is recommended that the sketch uses the same FS and ODR settings as the calibration
program
 *
 * Menu operation: type a letter in the input box of the serial monitor followed by enter
 *
 * written by Femme Verbeek 6 July 2020
 *
 * This program uses V2 of the LSM9DS1 library
 * Tested on an Arduino Nano 33 BLE Sense board.
 *
 *
 */

#include <Arduino_LSM9DS1.h>


const float accelCriterion = 0.1;
char xyz[3]= {'X','Y','Z'};
float maxAX = 1, maxAY=1, maxAZ=1, minAX=-1, minAY=-1, minAZ=-1; // Accel Slope
float zeroAX1 =0,zeroAX2 =0,zeroAY1 =0,zeroAY2 =0,zeroAZ1 =0,zeroAZ2 =0;  //Accel Offset
boolean accelOK=false;
uint8_t acceMMlOK=0; // bit 0..2 maxXYZ bit 3..5 minXYZ
uint8_t accelODRindex=5; // Sample Rate 0:off, 1:10Hz, 2:50Hz, 3:119Hz, 4:238Hz, 5:476Hz,
(6:952Hz=na)
uint8_t accelFSindex=3;   // Full Scale// 0: ±2g ; 1: ±24g ; 2: ±4g ; 3: ±8g

void setup() {
  Serial.begin(115200);
  while (!Serial);
  pinMode(LED_BUILTIN,OUTPUT);
  delay(10);
  if (!IMU.begin()) { Serial.println(F("Failed to initialize IMU!")); while (1);  }
  IMU.setAccelFS(accelFSindex);
  IMU.setAccelODR(accelODRindex);
  calibrateAccelMenu();
}

void loop(){ }

void printParam(char txt[], float param[3])
{   for (int i= 0; i<=2 ; i++)
    {  Serial.print(txt);Serial.print("[");
       Serial.print(i);Serial.print("] = ");
       Serial.print(param[i],6);Serial.print(";");
    }
}
void printSetParam(char txt[], float param[3])
{   Serial.print(txt);Serial.print("(");
    Serial.print(param[0],6);Serial.print(", ");
    Serial.print(param[1],6);Serial.print(", ");
    Serial.print(param[2],6);Serial.print(");");
}
//*************************************************************************************************
************************************
//*****************************************             Accelerometer
*******************************************
//*************************************************************************************************
************************************

void calibrateAccelMenu()
{char incomingByte = 0;
 byte b;
 uint16_t NofCalibrationSamples = 1000;
 while (1)  //(incomingByte!='X')
```

```
 {  Serial.println(F("\n\n"));
    Serial.println(F(" Calibrate Accelerometer Offset and Slope"));
    Serial.println(F(" Before calibrating choose the Full Scale (FS) setting and Output Data
Rate (ODR). The accelerometer and the"));
    Serial.println(F(" gyroscope share their ODR, so the setting here must be the same as in
the DIY_Calibration_Gyroscope sketch."));
    Serial.println(F(" Place the board on a horizontal surface with one of its axes vertical
and hit enter to start a calibration"));
    Serial.println(F(" measurement. Each of the axes must be measured pointing up and pointing
down, so a total of 6 measurements."));
    Serial.println(F(" The program recognises which axis is vertical and shows which were
measured successfully. If the angle is to"));
    Serial.println(F(" far oblique the measurement is not valid.\n  "));
    Serial.println(F(" (enter)  Start a calibration measurement. "));
    Serial.print  (F("   (N)    Number of calibration samples
"));Serial.println(NofCalibrationSamples);
    Serial.print  (F("   (F)    Full Scale setting
"));Serial.print(accelFSindex);Serial.print(" =
");Serial.print(IMU.getAccelFS(),0);Serial.println(F("g"));
    Serial.print  (F("   (R)    Output Data Rate (ODR) setting
"));Serial.print(accelODRindex);Serial.print(" =
");Serial.print(IMU.getAccelODR(),0);Serial.println(F("Hz (actual value)"));

//    Serial.println("Press (X) to exit \n");

    Serial.print(F(" Measured status of axis \n "));
    for (int i=0;i<=2;i++){  Serial.print(xyz[i]); if (bitRead(acceMMlOK,i)==1)Serial.print("+
= ( -OK- ) "); else Serial.print("+ = not done "); }
    Serial.print("\n ");
    for (int i=0;i<=2;i++){  Serial.print(xyz[i]); if
(bitRead(acceMMlOK,i+3)==1)Serial.print("- = ( -OK- ) "); else Serial.print("- = not done ");
}

 //   Serial.println(F("\n\nCurrent  accelerometer calibration values (copy/paste-able)\n"));
    Serial.println(F("\n\n   // Accelerometer code"));
    Serial.print(F("   IMU.setAccelFS(")); Serial.print(accelFSindex);
    Serial.print(F(");\n
IMU.setAccelODR("));Serial.print(accelODRindex);Serial.println(");");

    printSetParam("   IMU.setAccelOffset",IMU.accelOffset);
    Serial.println();
    printSetParam ("   IMU.setAccelSlope ",IMU.accelSlope);
    Serial.println("\n\n");
    incomingByte= readChar();                          //wait for and get keyboard input
    switch (incomingByte)
    { case  'F': { Serial.print (F("\n\nEnter new FS nr  0: ±2g ; 1: ±24g ; 2: ±4g ; 3: ±8g >
"));
                  b= readChar()-48; Serial.println(b);
                  if (b!=accelFSindex && b >=0 && b<=3) accelFSindex=b;
                  IMU.setAccelFS(accelFSindex);
                  Serial.print("\n\n\n\n\n\n\n\n\n");
                  break;}
      case 'R': { Serial.print (F("\n\nEnter new ODR nr   1:10,2:50 3:119,4:238,5:476 Hz >
"));
                  b= readChar()-48; //Serial.println(b);
                  if (b!=accelODRindex && b>=1 && b<=5) accelODRindex=b;
                  IMU.setAccelODR(accelODRindex);
                  Serial.print("\n\n\n\n\n\n\n\n\n");
                  break;
                }
      case 'N': { readAnswer("\n\n\n\n\n\nThe number of calibration samples ",
NofCalibrationSamples);
                  break;}
      case 'C': {};
      default :   calibrateAccel(NofCalibrationSamples);
    }
  }
}

void calibrateAccel(uint16_t NofSamples)
{  boolean validMmt=false;
```

```
   float x,y,z;
   Serial.println(F("\n\n\n\n\n\n\n\n\n\n\n"));
   Serial.println(F("measuring \n"));
//   IMU.setAccelODR(5);  //476 Hz
   raw_N_Accel(NofSamples,x,y,z);
   if (abs(x)>max(abs(y),abs(z)))
   {    Serial.println(F("X detected"));
       if (sqrt(y*y+z*z)/x<accelCriterion)
       {  validMmt= true;
          if (x>0) {maxAX=x;
                    acceMMlOK=acceMMlOK | 0b00000001 ;}
          else     {minAX=x;
                    acceMMlOK=acceMMlOK | 0b00001000 ; }
       }
   }
   if (abs(y)>max(abs(x),abs(z)))
   {  Serial.println(F("Y detected"));
      if (sqrt(x*x+z*z)/y<accelCriterion)
       {  validMmt= true;
          if (y>0) {maxAY=y;
                    acceMMlOK=acceMMlOK | 0b00000010 ; }
          else     {minAY=y;
                    acceMMlOK=acceMMlOK | 0b00010000 ; }
       }
   }
   if (abs(z)>max(abs(x),abs(y)))
   {  Serial.println(F("Z detected"));
      if ( sqrt(x*x+y*y)/z<accelCriterion)
       {  validMmt= true;
          if (z>0) {maxAZ=z;
                    acceMMlOK=acceMMlOK | 0b00000100 ; }
          else     {minAZ=z;
                    acceMMlOK=acceMMlOK | 0b00100000 ; }
       }
   }
   IMU.setAccelOffset((maxAX+minAX)/2,(maxAY+minAY)/2,(maxAZ+minAZ)/2);
   IMU.setAccelSlope ((maxAX-minAX)/2,(maxAY-minAY)/2,(maxAZ-minAZ)/2);
   if (acceMMlOK==0b00111111) accelOK = true;

   if ( !validMmt )
    { Serial.print(F("\n\n\nNot a valid measurement!  "));
      Serial.println(" x=");Serial.print(x);Serial.print("
y=");Serial.print(y);Serial.println("  z=");Serial.print(z);
    }
}

char readChar()
{  char ch;
   while (!Serial.available()) ;             // wait for character to be entered
   ch= toupper(Serial.read());
   delay(10);
   while (Serial.available()){Serial.read();delay(1);} // empty readbuffer
   return ch;
}

void readAnswer(char msg[], uint16_t& param)
{ char ch=0;
  byte count=0;
  const byte NofChars = 8;
  char ans[NofChars];
  while (Serial.available()){Serial.read();}  //empty read buffer
  Serial.print(msg);
  Serial.print(param);
  Serial.print(F(" Enter new value "));
  while (byte(ch)!=10 && byte(ch)!=13 && count<(NofChars-1)   )
  {  if (Serial.available())
     {  ch= Serial.read();
        ans[count]=ch;
        count++;
     }
  }
```

```
  ans[count]=0;
  Serial.println(ans);
  if (count>1) param= atoi(ans);
  while (Serial.available()){Serial.read();}
     Serial.println(F("\n\n\n\n\n\n\n"));
}



void raw_N_Accel(uint16_t N, float& averX, float& averY, float& averZ)
{    float x, y, z;
     averX=0; averY =0;averZ =0;
     for (int i=1;i<=N;i++)
     {  while (!IMU.accelAvailable());
        IMU.readRawAccel(x, y, z);
        averX += x;    averY += y;     averZ += z;
        digitalWrite(LED_BUILTIN, (millis()/125)%2);       // blink onboard led every 250ms
        if ((i%30)==0)Serial.print('.');
     }
     averX /= N;    averY /= N;     averZ /= N;
     digitalWrite(LED_BUILTIN,0);                          // led off
}
```

Gyroscope Calibration:

```
/* DIY calibration program for the LSM9DS1 chip
 *
 * Follow the instructions on the screen how to do calibration measurements.
 * Menu operation: type a letter in the input box of the serial monitor followed by enter.
 * See instruction video https://youtu.be/BLvYFXoP33o
 * No special tools or setups are needed, however it is handy if the board with the LSM9DS1
chip is fitted inside
 * a non-metalic rectangular box.
 *
 * Each new instance of the LSM9DS1 chip will require it's own unique set of calibration
factors.
 * For an improved accuracy it is recommended that the sketch and the calibration program use
the same settings for
 * Full Scale (FS) and Output Data rate (ODR). This is the reasin why the possibility was
added in this program.
 * The settings and calibration factors are displayed on screen as code that can be
copy/pasted
 * directly into a sketch.
 *
 *         Gyroscope Calibration
 * The program starts with a short menu that offers the possibility to change the FS and ODR
value.
 * Next the Offset must be measured. This takes only a few seconds, during which the board
must be kept still.
 * This also enables the next step, which is to calibrate the slope. During a slope
calibration the sensor must be rotated
 * calmly about one axis over a known angle. This angle can be changed to your convenience. A
larger angle is more accurate,
 * but more difficult to do. The rotation can be done by hand. It must must be pure, without
much rotation about the other
 * two axes. e.g. by keeping the board on a flat surface with the rotation axis vertical while
turning is good enough.
 * Press Enter to finish the measurement.
 * Each of the axes X,Y and Z must be measured, so in total three measurements. The program
automatically detects which
 * and shows this on screen. The rotation direction clockwise or anti-clockwise is
unimportant, both directions will work.
 * It is important that the offset is measured before the slope calibration. If for some
reason the offset has to be remeasured
 * make sure you remeasure the slope as well
 *
 *
 * written by Femme Verbeek 6 July 2020
 *
 * This program uses V2 of the LSM9DS1 library
 * Tested on an Arduino Nano 33 BLE Sense board.
```

```
 */

#include <Arduino_LSM9DS1.h>

const float gyroSlopeCriterion = 50;  //Smaller value requires more pureness of the rotation
char xyz[3]= {'X','Y','Z'};
boolean gyroOffsetOK=false;
boolean gyroSlopeOK[3]={false,false,false};
uint8_t gyroODRindex=5;
uint8_t gyroFSindex=2;   // (0= ±245 dps; 1= ±500 dps; 2= ±1000 dps; 3= ±2000 dps)

void setup() {
  Serial.begin(115200);
  while (!Serial);
  pinMode(LED_BUILTIN,OUTPUT);
  delay(10);
  if (!IMU.begin()) { Serial.println(F("Failed to initialize IMU!"));while (1); }
  IMU.setGyroODR(gyroODRindex);   //238Hz
  IMU.setGyroFS(gyroFSindex);
  calibrateGyroMenu();
}

void loop() { }

/*void printParam(char txt[], float param[3])
{   for (int i= 0; i<=2 ; i++)
    {  Serial.print(txt);Serial.print("[");
       Serial.print(i);Serial.print("] = ");
       Serial.print(param[i],6);Serial.print(";");
    }
}*/

void printSetParam(char txt[], float param[3])
{   Serial.print(txt);Serial.print("(");
    Serial.print(param[0],6);Serial.print(", ");
    Serial.print(param[1],6);Serial.print(", ");
    Serial.print(param[2],6);Serial.print(");");
}

//*************************************************************************************************
************************************
//*****************************************             Gyroscope
******************************************
//*************************************************************************************************
************************************


void calibrateGyroMenu()
{ char incomingByte = 0;
  byte b;
  uint16_t turnangle = 180;
  uint16_t NofCalibrationSamples = 1000;
  while (1)//    (incomingByte!='X')
  {
    if (!gyroOffsetOK)
    {  Serial.println(F("\n\nStep 1       CALIBRATE GYROSCOPE OFFSET "));
       Serial.println(F("First choose the sample frequency (ODR) and the Full Scale value. The
accelerometer and the gyroscope"));
       Serial.println(F("share their ODR, so the setting here must be the same as in the
DIY_Calibration_Gyroscope sketch."));
       Serial.println(F("This is far more important for the Gyroscope than for the
accelerometer. "));
       Serial.println(F("Next enter \"O\" to start the gyroscope offset measurement. \nDuring
this offset measurement the sensor must be kept still.\n"));
    } else
    {  Serial.println(F("\n\nStep 2       CALIBRATE GYROSCOPE SLOPE"));
       Serial.println(F("During a slope calibration the sensor must be rotated calmly about
one axis over a known angle."));
       Serial.println(F("Change the angle to your convenience. A larger angle is more
accurate, but more difficult to do."));
```

```
       Serial.println(F("The rotation must be pure, without much rotation about the other two
axes. It can be done by hand."));
       Serial.println(F("Keeping the board on a flat surface with the rotation axis vertical
while turning is good enough."));
       Serial.println(F("For an accurate result you can start and end with its side pushed
against a non moving object."));
       Serial.println(F("When you're done turning the sensor, press (Enter) to stop measuring.
Each of the axes X,Y and Z "));
       Serial.println(F("must be measured. The program automatically detects which. \n"));

       Serial.println(F(" (A) Change the measuring angle to turn the board"));
       Serial.print  (F(" (C) Calibrate Slope ==>> Turn the board over
"));Serial.print(turnangle);Serial.println(F("° and press enter when finished "));
    }  Serial.print  (F(" (F) Full Scale setting "));Serial.print(gyroFSindex);Serial.print("
= "); Serial.print(IMU.getGyroFS(),0);Serial.println(F("°/s"));
       Serial.print  (F(" (R) Output Data Rate (ODR) setting
"));Serial.print(gyroODRindex);Serial.print(" =
");Serial.print(IMU.getGyroODR(),0);Serial.println(F("Hz (actual value)"));
       Serial.print  (F(" (N) Number of calibration samples
"));Serial.println(NofCalibrationSamples);
       Serial.println(F(" (O) Calibrate Offset (keep board still during measurement)"));

       Serial.println(F("\nOffset calibration ( -OK- )"));
       Serial.print  (F("Slope calibration axis  " ));
       for (int i= 0; i<=2 ; i++)
       {   Serial.print(xyz[i]);
           if (gyroSlopeOK[i]) Serial.print(F("= ( -OK- ) ")); else Serial.print(F("= not done
"));
       }
    Serial.println(F("\n\n   // Gyroscope code"));
    Serial.print  (F    ("   IMU.setGyroFS("));   Serial.print(gyroFSindex);
    Serial.print(  F(");\n
IMU.setGyroODR("));Serial.print(gyroODRindex);Serial.println(");");
    printSetParam("   IMU.setGyroOffset ",IMU.gyroOffset);
    Serial.println();
    printSetParam("   IMU.setGyroSlope ",IMU.gyroSlope);
    Serial.println();
    incomingByte= readChar();
    switch (incomingByte)
    { case 'A': { readAnswer("\n\n\n\n\n\nMeasurement turnangle for the board ", turnangle);
                  break;}
      case 'C': { Serial.print(F("\n\n\n\n\n\nMeasuring. Turn the sensor over
"));Serial.print(turnangle);Serial.println(F(" degrees\n"));
                  Serial.println(F("Press Enter when finished."));
                  calibrateGyroslope(turnangle);
                  break;}
      case 'F': { Serial.print (F("\n\nEnter new FS nr  0: ±245 1: ±500 2: ±1000 3:± 2000 dps
> "));
                  b= readChar()-48; Serial.println(b);
                  if (b!=gyroFSindex && b >=0 && b<=3) gyroFSindex=b;
                  IMU.setGyroFS(gyroFSindex);
                  gyroOffsetOK=false;
                  Serial.print("\n\n\n");
                  break;}
      case 'R': { Serial.print (F("\n\nEnter new ODR nr   1:10,2:50 3:119,4:238,5:476 Hz> "));
                  b= readChar()-48; //Serial.println(b);
                  if (b!=gyroODRindex && b>=1 && b<=5)
                  {   gyroODRindex=b;
                      IMU.setGyroODR(gyroODRindex);
                      gyroOffsetOK=false;
                  }
                  Serial.print("\n\n\n");
                  break;
                }
      case 'N': { readAnswer("\n\n\n\n\n\nThe number of calibration samples ",
NofCalibrationSamples);
                  break;}
      case 'O': { calibrateGyroOffset(NofCalibrationSamples);     }
    }
   Serial.println("");
  }
```

```
}

void calibrateGyroOffset(uint16_t N)  // don't move the board during calibration
{  float x, y, z;// , addX=0, addY=0, addZ=0  ;
   Serial.println(F("\n\n\n\nMeasuring offset. Just a moment."));
   Serial.println(F("\n\nKeep the board still during measurement"));
   raw_N_Gyro(N,x,y,z);
   IMU.setGyroOffset(x, y,z); // Store the average measurements as offset
   Serial.print("\n\n\n\n\n");
   gyroOffsetOK=true;
}

void calibrateGyroslope(unsigned int turnangle)  // rotate board over known angle
{  boolean validMmt=false;
   float dirX=0, dirY=0, dirZ=0,sigmaX2=0,sigmaY2=0,sigmaZ2=0;
   float x, y, z, maxXYZ;
   unsigned int count=0;
   while (!Serial.available())         // measure until enter key pressed
   {  while (!IMU.gyroAvailable());
       IMU.readRawGyro(x, y, z);
       dirX += (x - IMU.gyroOffset[0])/IMU.getGyroODR();    // slope is still raw but offset
must already be calibrated
       dirY += (y - IMU.gyroOffset[1])/IMU.getGyroODR();
       dirZ += (z - IMU.gyroOffset[2])/IMU.getGyroODR();
       sigmaX2 +=x*x;  sigmaY2+=y*y;  sigmaZ2+=z*z;
       if (count==0) maxXYZ= abs(x);
       maxXYZ= max(maxXYZ,abs(x)); maxXYZ= max(maxXYZ,abs(y)); maxXYZ= max(maxXYZ,abs(z));
       count++;
       if ((count%30)==0)Serial.print('.');
       digitalWrite(LED_BUILTIN, (millis()/125)%2);       // blink onboard led every 250ms
   }
   digitalWrite(LED_BUILTIN,0);       // led off
   Serial.readStringUntil(13);        //Empty read buffer
   Serial.print(F("\n\n\nMeasured direction change X "));
   Serial.print(dirX,6);Serial.print("°\tY "); Serial.print(dirY,6);Serial.print("°\t Z ");
Serial.println(dirZ,6);Serial.print("°");
   sigmaX2 /= count;    sigmaY2 /= count;    sigmaZ2 /= count;
   Serial.print(F("Std.dev. "));
   Serial.print(sigmaX2,6);Serial.print('\t'); Serial.print(sigmaY2,6);Serial.print('\t');
Serial.println(sigmaZ2,6);
   Serial.print(F("percentage of Full Scale "));
Serial.print(100*maxXYZ/IMU.getGyroFS());Serial.println('%');
   if (maxXYZ/IMU.getGyroFS()>0.95) Serial.print(F("Maximum rotation speed reached. Choose a
different FS setting or turn more slowly."));
   else
   { dirX=abs(dirX); dirY=abs(dirY); dirZ=abs(dirZ);
     if (dirX>max(dirY,dirZ))
     { if (sigmaY2<gyroSlopeCriterion && sigmaZ2<gyroSlopeCriterion )
       {  validMmt= true;
          IMU.gyroSlope[0]=turnangle/dirX;
          gyroSlopeOK[0]=true;
          Serial.print ("Valid measurement, X detected, slope ");  Serial.println
(IMU.gyroSlope[0]);
       }
     }
     if (dirY>max(dirX,dirZ))
     { if (sigmaX2<gyroSlopeCriterion && sigmaZ2<gyroSlopeCriterion )
       {  validMmt= true;
          IMU.gyroSlope[1]=turnangle/dirY;
          gyroSlopeOK[1]=true;
          Serial.print ("Valid measurement, Y detected, slope ");Serial.println
(IMU.gyroSlope[1]);
       }
     }
     if (dirZ>max(dirY,dirX))
     { if (sigmaY2<gyroSlopeCriterion && sigmaX2<gyroSlopeCriterion )
       {  validMmt= true;
          IMU.gyroSlope[2]=turnangle/dirZ;
          gyroSlopeOK[2]=true;
          Serial.print ("Valid measurement, Z detected, slope ");Serial.println
(IMU.gyroSlope[2]);
```

```
      }
    }
  }
  if ( !validMmt )
  { Serial.println(F("\n\nNot a valid measurement!"));
    delay(2000);
  }
  else Serial.println("\n\n");
}


char readChar()
{  char ch;
   while (!Serial.available()) ;             // wait for character to be entered
   ch= toupper(Serial.read());
   delay(10);
   while (Serial.available()){Serial.read();delay(1);} // empty readbuffer
   return ch;
}

void readAnswer(char msg[], uint16_t& param)
{ char ch=0;
  byte count=0;
  const byte NofChars = 8;
  char ans[NofChars];
//  float val;
  while (Serial.available()){Serial.read();}  //empty read buffer
  Serial.print(msg);
  Serial.print(param);
  Serial.print(F(" Enter new value "));
  while (byte(ch)!=10 && byte(ch)!=13 && count<(NofChars-1)   )
  {  if (Serial.available())
     {  ch= Serial.read();
        ans[count]=ch;
        count++;
     }
  }
  ans[count]=0;
  Serial.println(ans);
  if (count>1) param= atoi(ans);
  while (Serial.available()){Serial.read();}
     Serial.println("\n\n\n\n\n\n\n");
}

void raw_N_Gyro(unsigned int N, float& averX, float& averY, float& averZ)
{    float x, y, z;
     averX=0; averY =0;averZ =0;
     for (int i=1;i<=N;i++)
     {  while (!IMU.gyroAvailable());
        IMU.readRawGyro(x, y, z);
        averX += x;    averY += y;     averZ += z;
        digitalWrite(LED_BUILTIN, (millis()/125)%2);       // blink onboard led every 250ms
        if ((i%30)==0)Serial.print('.');
     }
     averX /= N;    averY /= N;     averZ /= N;
     digitalWrite(LED_BUILTIN,0);                          // led off
}
```

Magnetometer Calibration:

```
/*          DIY calibration program for the LSM9DS1 chip
 *
 * Follow the instructions on the screen how to do calibration measurements.
 * See instruction video https://youtu.be/BLvYFXoP33o
 * No special tools or setups are needed, however it is handy if the board with the LSM9DS1
chip is fitted inside
 * a non-metalic rectangular box with flat sides.
 * The offset and slope factors are displayed on screen as code that can be copy/pasted
directly into a sketch.
 * Each new instance of the chip will require it's own unique set of calibration factors.
 *
```

```
 * To operate the menu in the IDE serial monitor you must press a letter key followed by Enter
 *
 *                     Magnetometer
 * During calibration of the Magnetometer each of it's sensor axes X, Y and Z must be aimed in
both ways (positive
 * and negative direction) parallel to the earth magnetic field lines.
 * It helps a lot if you know roughly what this direction is.
 * Info about the Earthmagnetic field https://en.wikipedia.org/wiki/Earth's_magnetic_field
 * The angle above the horizon is called the inclination angle. If you live in the northern
hemisphere roughly in
 * southern direction, and in the southern hemisphere roughly in northern direction.
 *
 * written by Femme Verbeek 30-5-2020
 *
 * This program uses V2 of the LSM9DS1 library
 * Tested on an Arduino Nano 33 BLE Sense board.
 */

#include <Arduino_LSM9DS1.h>


float EarthMagnetStrength = 49.0;  //= µT

boolean magnetOK=false;
uint8_t magnetODRindex=8;  // (0..8)->{0.625,1.25,2.5,5.0,10,20,40,80,400}Hz
uint8_t magnetFSindex=0;   // 0=±400.0; 1=±800.0; 2=±1200.0 , 3=±1600.0  (µT)


void setup() {
  Serial.begin(115200);
  while (!Serial);
  pinMode(LED_BUILTIN,OUTPUT);
  delay(10);
  if (!IMU.begin()) { Serial.println(F("Failed to initialize IMU!")); while (1);  }
  IMU.setMagnetODR(magnetODRindex);
  IMU.setMagnetFS(magnetFSindex);
}

void loop()
{ // MainMenu();
  calibrateMagnetMenu();
}

void printParam(char txt[], float param[3])
{   for (int i= 0; i<=2 ; i++)
    {  Serial.print(txt);Serial.print("[");
       Serial.print(i);Serial.print("] = ");
       Serial.print(param[i],6);Serial.print(";");
    }
}

void printSetParam(char txt[], float param[3])
{   Serial.print(txt);Serial.print("(");
    Serial.print(param[0],6);Serial.print(", ");
    Serial.print(param[1],6);Serial.print(", ");
    Serial.print(param[2],6);Serial.print(");");
}

//*****************************************************************************************
**********************************
//*****************************************          Magnetometer
*****************************************
//*****************************************************************************************
**********************************


void calibrateMagnetMenu()
{ char incomingByte = 0;
  byte b;
 // String ans;
    Serial.println(F("\n\n\n\n\n\n\n\n\n\n\n\n"));
```

```
 while (1)   //(incomingByte!='X')
{   Serial.println(F("Calibrate Magnetometer"));
    Serial.println(F("During measurement each of the sensor XYZ axes must be aligned in both
directions with the Earth's magnetic field."));
    Serial.println(F("This takes about 10 seconds, if you know the local direction of the
magnetic field lines. If you don't, it will take"));
    Serial.println(F("several minutes, as you have to twist the board around, aiming every
axis in every direction until the min and max "));
    Serial.println(F("values no longer change. Info about the Earthmagnetic field
https://en.wikipedia.org/wiki/Earth's_magnetic_field "));
    Serial.println(F("E.g. in my case (Northern hemisphere)declination=0°, inclination=67°,
means the aiming direction is South and a"));
    Serial.println(F("rather steep 67° above the horizon. "));
    Serial.println(F("The magnetic field measurement will be heavily disturbed by your set-up,
so an \"in-situ\" calibration is advised.\n"));
    Serial.print  (F(" (F) Full Scale setting "));Serial.print(magnetFSindex);Serial.print(" =
±"); Serial.print(IMU.getMagnetFS(),0);Serial.println(F(" µT"));
    Serial.print  (F(" (R) Output Data Rate (ODR) setting
"));Serial.print(magnetODRindex);Serial.print(" =
");Serial.print(IMU.getMagnetODR(),0);Serial.println(F("Hz (actual value)"));
    Serial.print  (F(" (L) Local intensity of Earth magnetic field
"));Serial.print(EarthMagnetStrength);Serial.println(F(" µT  Change into your local value."));
    Serial.println(F(" (C) Calibrate Magnetometer, Twist board around to find min-max values
or aim along earth mag field,  press enter to stop\n"));

    Serial.println(F("   // Magnetometer code"));
    Serial.print  (F("   IMU.setMagnetFS("));Serial.print(magnetFSindex);Serial.println(");");
    Serial.print  (F("
IMU.setMagnetODR("));Serial.print(magnetODRindex);Serial.println(");");
    printSetParam("   IMU.setMagnetOffset",IMU.magnetOffset);
    Serial.println();
    printSetParam("   IMU.setMagnetSlope ",IMU.magnetSlope);
    Serial.println(F("\n\n"));
    incomingByte= readChar();
    switch (incomingByte)
    { case 'L': { readAnswer("\n\nLocal Earth Magnetic Field intensity  " ,EarthMagnetStrength
);   break;}
      case 'C': { calibrateMagnet() ;
                  Serial.print(F("\n\n\n\n\n\n"));
                  break;}
      case 'F': { Serial.print (F("\n\nEnter new FS nr 0=±400.0; 1=±800.0; 2=±1200.0 ,
3=±1600.0  (µT)> "));
                  b= readChar()-48; Serial.println(b);
                  if (b!=magnetFSindex && b >=0 && b<=3) magnetFSindex=b;
                  IMU.setMagnetFS(magnetFSindex);
                  Serial.print("\n\n\n");
                  break;}
      case 'R': { Serial.print (F("\n\nEnter new ODR nr 6: 40Hz, 7: 80Hz, 8: 400Hz not adviced
0..5: 0.625,1.25,2.5,5.0,10,20 Hz  "));
                  b= readChar()-48; Serial.println(b);
                  if (b!=magnetODRindex && b>=1 && b<=8) magnetODRindex=b;
                  IMU.setMagnetODR(magnetODRindex);
                  Serial.print("\n\n\n\n\n\n\n\n\n");
                  break;
                }
      default : {Serial.println(F("No menu choise\n\n"));Serial.print(incomingByte); break;}
    }
  }
}


char readChar()
{  char ch;
   while (!Serial.available()) ;             // wait for character to be entered
   ch= toupper(Serial.read());
   delay(10);
   while (Serial.available()){Serial.read();delay(1);} // empty readbuffer
   return ch;
}

void readAnswer(char msg[], float& param)
```

```
{ char ch=0;
  byte count=0;
  const byte NofChars = 8;
  char ans[NofChars];
  while (Serial.available()){Serial.read();}  //empty read buffer
  Serial.print(msg);
  Serial.print(param);
  Serial.print(F(" Enter new value "));
  while (byte(ch)!=10 && byte(ch)!=13 && count<(NofChars-1)   )
  {  if (Serial.available())
     {  ch= Serial.read();
        ans[count]=ch;
        count++;
     }
  }
  ans[count]=0;
  Serial.println(ans);
  if (count>1) param= atof(ans);
  while (Serial.available()){Serial.read();}
     Serial.println(F("\n\n\n\n\n\n\n"));
}


void calibrateMagnet()  // measure Offset and Slope of XYZ
{  float x, y, z, Xmin, Xmax, Ymin, Ymax, Zmin, Zmax  ;
   unsigned long count=0;
   IMU.setMagnetODR(8);    //Fast rate 400Hz
   raw_N_Magnet(10, Xmin, Ymin, Zmin);             // find some starting values
   Xmax = Xmin; Ymax = Ymin; Zmax = Zmin;
   while (!Serial.available())                      // measure until enter key pressed
   {  raw_N_Magnet(10, x, y, z);                    //average over a number of samples to
reduce the effect of outlyers
      Xmax = max (Xmax, x); Xmin = min (Xmin, x);
      Ymax = max (Ymax, y); Ymin = min (Ymin, y);
      Zmax = max (Zmax, z); Zmin = min (Zmin, z);
      count++;
      if ((count & 5)==0)                           //reduce the number of prints by a factor
      { Serial.print(F("Xmin = "));Serial.print(Xmin); Serial.print(F("  Xmax =
"));Serial.print(Xmax);
        Serial.print(F(" Ymin = "));Serial.print(Ymin); Serial.print(F("  Ymax =
"));Serial.print(Ymax);
        Serial.print(F(" Zmin = "));Serial.print(Zmin); Serial.print(F("  Zmax =
"));Serial.print(Zmax);
        Serial.println();
      }
   }
   while (Serial.available()) Serial.read();    //readStringUntil(13);        //Empty read
buffer
   IMU.setMagnetOffset( (Xmax+Xmin)/2,(Ymax+Ymin)/2, (Zmax+Zmin)/2 ) ;
// store offset
   IMU.setMagnetSlope (
(2*EarthMagnetStrength)/(Xmax-Xmin),(2*EarthMagnetStrength)/(Ymax-Ymin),(2*EarthMagnetStrength
)/(Zmax-Zmin));  // store slope
   magnetOK=true;
   IMU.setMagnetODR(magnetODRindex);
}


void raw_N_Magnet(unsigned int N, float& averX, float& averY, float& averZ)
{    float x, y, z;
     averX=0; averY =0;averZ =0;
     for (int i=1;i<=N;i++)
     {  while (!IMU.magnetAvailable());
        IMU.readRawMagnet(x, y, z);
        averX += x;    averY += y;     averZ += z;
        digitalWrite(LED_BUILTIN, (millis()/125)%2);       // blink onboard led every 250ms
        if ((i%30)==0)Serial.print('.');
     }
     averX /= N;    averY /= N;     averZ /= N;
     digitalWrite(LED_BUILTIN,0);                         // led off
}
```

Data Collection Code:

```
// Massive Data Collection
#include <Wire.h>
#include <SPI.h>
#include <Adafruit_LSM9DS1.h>
#include <Adafruit_Sensor.h>  // not used in this demo but required!

// i2c
Adafruit_LSM9DS1 lsm = Adafruit_LSM9DS1();

#define LSM9DS1_SCK A5
#define LSM9DS1_MISO 12
#define LSM9DS1_MOSI A4
#define LSM9DS1_XGCS 6
#define LSM9DS1_MCS 5
// You can also use software SPI
//Adafruit_LSM9DS1 lsm = Adafruit_LSM9DS1(LSM9DS1_SCK, LSM9DS1_MISO, LSM9DS1_MOSI,
LSM9DS1_XGCS, LSM9DS1_MCS);
// Or hardware SPI! In this case, only CS pins are passed in
//Adafruit_LSM9DS1 lsm = Adafruit_LSM9DS1(LSM9DS1_XGCS, LSM9DS1_MCS);

  //Onboard IUM
  #include <Arduino_LSM9DS1.h>
  boolean viewInSerialPlotter=false;      //true optimises for serial plotter, false for
serial monitor

  //MADgwick
  // based off of Tom Igoe's version here :
https://itp.nyu.edu/physcomp/lessons/accelerometers-gyros-and-imus-the-basics
#include "MadgwickAHRS.h"

// initialize a Madgwick filter:
Madgwick filter;
// sensor's sample rate is fixed at 104 Hz:
const float sensorRate = 104.00;

//Servo

int servoPin = A0;      // defines servo signal pin, power snd ground
int onboardLEDPin = 13;  // defines the pin of the onboard LED
int servoValue;

//
//void setupSensor()
//{
//  // 1.) Set the accelerometer range
//  //lsm.setupAccel(lsm.LSM9DS1_ACCELRANGE_2G);
//  //lsm.setupAccel(lsm.LSM9DS1_ACCELRANGE_4G);
//  //lsm.setupAccel(lsm.LSM9DS1_ACCELRANGE_8G);
//  lsm.setupAccel(lsm.LSM9DS1_ACCELRANGE_16G);
//
//  // 2.) Set the magnetometer sensitivity
//  //lsm.setupMag(lsm.LSM9DS1_MAGGAIN_4GAUSS);
//  //lsm.setupMag(lsm.LSM9DS1_MAGGAIN_8GAUSS);
//  //lsm.setupMag(lsm.LSM9DS1_MAGGAIN_12GAUSS);
//  lsm.setupMag(lsm.LSM9DS1_MAGGAIN_16GAUSS);
//
//  // 3.) Setup the gyroscope
//  //lsm.setupGyro(lsm.LSM9DS1_GYROSCALE_245DPS);
//  //lsm.setupGyro(lsm.LSM9DS1_GYROSCALE_500DPS);
//  lsm.setupGyro(lsm.LSM9DS1_GYROSCALE_2000DPS);
//}


void setup()
{
  //LMS9DS1 Setup
//  Serial.begin(115200);
//
```

```
//  while (!Serial) {
//    delay(1); // will pause Zero, Leonardo, etc until serial console opens
//  }
//
//  Serial.println("LSM9DS1 data read demo");
//
//  // Try to initialise and warn if we couldn't detect the chip
//  if (!lsm.begin())
//  {
//    Serial.println("Oops ... unable to initialize the LSM9DS1. Check your wiring!");
//    while (1);
//  }
//  Serial.println("Found LSM9DS1 9DOF");
//
//  // helper to just set the default scaling we want, see above!
//  setupSensor();



  //Onboard IMU
   Serial.begin(9600);
   pinMode(servoPin, OUTPUT);    // Sets the servo pin as an output
   pinMode(onboardLEDPin, OUTPUT); // Sets the onboard LED pin as an output
   while(!Serial);     // wait to execute loop program until the serial monitor is opened


   delay(100);
   if (!IMU.begin())
   { Serial.println("Failed to initialize IMU!");
     while (1);
   }

   //Acceleromter Setup
/*******************    For an improved accuracy run the DIY_Calibration_Accelerometer sketch
first.     ****************
*******************         Copy/Replace the lines below by the code output of the program
****************/
   IMU.setAccelFS(3);
   IMU.setAccelODR(5);
   //Calibration
   IMU.setAccelOffset(0.000990, -0.021752, -0.014393);
   IMU.setAccelSlope (1.001257, 0.994082, 1.004347);
/*****************************************************************************************
************************************
*******  FS  Full Scale         range 0:±2g | 1:±24g | 2: ±4g | 3: ±8g  (default=2)
******
*******  ODR Output Data Rate   range 0:off | 1:10Hz | 2:50Hz | 3:119Hz | 4:238Hz | 5:476Hz,
(default=3)(not working 6:952Hz) ******
*****************************************************************************************
************************************/
   IMU.accelUnit=  GRAVITY;    // or  METERPERSECOND2

//   if (!viewInSerialPlotter)
//   {  Serial.println("Gyroscope in degrees/second \n");
//      Serial.print("Accelerometer Full Scale = ±");
//      Serial.print(IMU.getAccelFS());
//      Serial.println ("g");
//      Serial.print("Accelerometer sample rate = ");
//      Serial.print(IMU.getAccelODR());        // alias  AccelerationSampleRate());
//      Serial.println(" Hz \n");
//      delay(4000);
//   }
   //Serial.println(" X \t Y \t Z ");

   //Gyroscope Setup
   /*******   The gyroscope needs to be calibrated. Offset controls drift and Slope scales the
measured rotation angle  *********
*****************   Copy/Replace the lines below by the output of the
DIY_Calibration_Gyroscope sketch   ********************/
   IMU.setAccelFS(3);
   IMU.setAccelODR(5);
```

```
   //Calibration
   IMU.setGyroOffset (0.000000, 0.000000, 0.000000);
   IMU.setGyroSlope (1.306100, 1.180107, 1.129232);

/*******************************************************************************************
*******************************
*********  FS  Full Scale       setting 0: ±245°/s | 1: ±500°/s | 2: ±1000°/s | 3: ±2000°/s
****************************
*********  ODR Output Data Rate setting 0:off | 1:10Hz | 2:50Hz | 3:119Hz | 4:238Hz | 5:476Hz,
(not working 6:952Hz)   *******
*******************************************************************************************
*******************************/
   IMU.gyroUnit= DEGREEPERSECOND;  //   DEGREEPERSECOND  RADIANSPERSECOND  REVSPERMINUTE
REVSPERSECOND
//   if (!viewInSerialPlotter)
//   {  Serial.println("Gyroscope in degrees/second \n");
//      Serial.print("Gyroscope Full Scale = ±");
//      Serial.print(IMU.getGyroFS());
//      Serial.println ("°/s");
//      Serial.print("Gyroscope sample rate = ");
//      Serial.print(IMU.getGyroODR());        //alias  IMU.gyroscopeSampleRate());
//      Serial.println(" Hz");
//      delay(4000);
//   }
   //Serial.println("X \t Y \t Z");

   //Magnetometer Setup
   /*****************   For a proper functioning of the magnetometer it needs to be calibrated
*******************
*****************   Replace the lines below by the output of the DIY_Calibration_Magnetometer
sketch   *******************/
   IMU.setMagnetFS(0);
   IMU.setMagnetODR(8);
   //Calibration
   IMU.setMagnetOffset(8.415527, 21.201172, 2.539063);
   IMU.setMagnetSlope (1.210446, 1.196091, 1.180751);
/*******************************************************************************************
*******************************
****  FS  Full Scale        range (0=±400 | 1=±800 | 2=±1200 | 3=±1600  (µT)
*****
****  ODR Output Data Rate  range (6,7,8)=(40,80,400)Hz | not available on all chips (0..5):
(0.625,1.25,2.5,5.0,10,20)Hz *****
*******************************************************************************************
*******************************/
   IMU.magnetUnit = MICROTESLA;  //   GAUSS   MICROTESLA   NANOTESLA

//   if (!viewInSerialPlotter)
//   {  Serial.println("Magnetic Field in µT");
//      Serial.print("Magnetometer Full Scale = ±");
//      Serial.print(IMU.getMagnetFS());
//      Serial.println ("µT");
//      Serial.print("Magnetic field sample rate = ");
//      Serial.print(IMU.getMagnetODR());        // alias IMU.magneticFieldSampleRate in
library version 1.01
//      Serial.println(" Hz");
//      delay(4000);
//   }
   //Serial.println("X \t Y\t Z");

   //MADgmwick
     // start the filter to run at the sample rate:
     filter.begin(sensorRate);

  Serial.println("\t X \t Y\t Z \t X \t Y\t Z \t X \t Y\t Z \t H \t P \t R");
  blinkNum(3);                  // call function blinkNum with numBlinks parameter
}


void loop()
{
  //LSM9DS1 Reading
```

```
//  lsm.read();  /* ask it to read in the data */
//
//  /* Get a new sensor event */
//  sensors_event_t a, m, g, temp;
//
//  lsm.getEvent(&a, &m, &g, &temp);
//
//  //Serial.print("Accel X: ");
//  Serial.print(a.acceleration.x);// Serial.print(" m/s^2");
//  Serial.print('\t');//Serial.print("\tY: ");
//  Serial.print(a.acceleration.y);     //Serial.print(" m/s^2 ");
//  Serial.print('\t');//Serial.print("\tZ: ");
//  Serial.print(a.acceleration.z);     //Serial.println(" m/s^2 ");
//
//  Serial.print('\t');
//
//  //Serial.print("Mag X: ");
//  Serial.print(m.magnetic.x);   //Serial.print(" uT");
//  Serial.print('\t');//Serial.print("\tY: ");
//  Serial.print(m.magnetic.y);     //Serial.print(" uT");
//  Serial.print('\t');//Serial.print("\tZ: ");
//  Serial.print(m.magnetic.z);     //Serial.println(" uT");
//
// Serial.print('\t');
//
//  //Serial.print("Gyro X: ");
//  Serial.print(g.gyro.x);   //Serial.print(" rad/s");
//  Serial.print('\t');//Serial.print("\tY: ");
//  Serial.print(g.gyro.y);      //Serial.print(" rad/s");
//  Serial.print('\t');//Serial.print("\tZ: ");
//  Serial.print(g.gyro.z);      //Serial.println(" rad/s");
//
//  Serial.print('\t');

  //Serial.println();
  //delay(200);

  //Onboard IMU Reading
  //Accelerometer

  //
  servoConstant();  // Call function servoConstant to hold the position of the servo static
  //


  float xA, yA, zA;

     Serial.print('\t');  //tab

  if (IMU.accelAvailable())                  // alias IMU.accelerationAvailable in library
version 1.01
  {  IMU.readAccel(xA, yA, zA);                 // alias IMU.readAcceleration  in library
version 1.01

     Serial.print(xA);
     Serial.print('\t');
     Serial.print(yA);
     Serial.print('\t');
     Serial.print(zA);
     Serial.print('\t');
  }
  //Gyroscope
    float xG, yG, zG;

  if (IMU.gyroAvailable())    // alias IMU.gyroscopeAvailable
  {
     IMU.readGyro(xG, yG, zG);   // alias IMU.readGyroscope
     Serial.print(xG);
     Serial.print('\t');
     Serial.print(yG);
     Serial.print('\t');
```

```
     Serial.print(zG);
     Serial.print('\t');
  }
  //Magnetometer
    float xM, yM, zM;

  if (IMU.magnetAvailable())                  // alias IMU.magneticFieldAvailable in library
version 1.01
  { IMU.readMagnet(xM, yM, zM);                  // alias IMU.readMagneticField in library
version 1.01

    Serial.print(xM);
    Serial.print('\t');
    Serial.print(yM);
    Serial.print('\t');
    Serial.print(zM);

    Serial.print('\t');
  }

   //MADgwick
  // values for acceleration and rotation:
  float xAcc, yAcc, zAcc;
  float xGyro, yGyro, zGyro;
  float xMag, yMag, zMag;

  // values for orientation:
  float roll, pitch, heading;
  // check if the IMU is ready to read:
  if (IMU.accelerationAvailable() &&
      IMU.gyroscopeAvailable() && IMU.magneticFieldAvailable()) {
    // read accelerometer &and gyrometer:
    IMU.readAcceleration(xAcc, yAcc, zAcc);
    IMU.readGyroscope(xGyro, yGyro, zGyro);
    IMU.readMagnet(xMag,yMag, zMag);

    // update the filter, which computes orientation:
    filter.update(xGyro, yGyro, zGyro, xAcc, yAcc, zAcc, xMag,yMag, zMag);

    // print the heading, pitch and roll
    roll = filter.getRoll();
    pitch = filter.getPitch();
    heading = filter.getYaw();
    //Serial.print("Orientation: ");
    Serial.print(heading);
    Serial.print('\t');//Serial.print(" ");
    Serial.print(pitch);
    Serial.print('\t');//Serial.print(" ");
    Serial.println(roll);
    }
}
//For testing individual positions
void servoConstant()
{
      int x = 0;  // Initialize x to zero
    while (x == 0)
    {
          digitalWrite(servoPin, HIGH);   // enable servo
          delayMicroseconds(400);    // Set servo position

          digitalWrite(servoPin, LOW);  // disable servo
          delay(20);                   // REQUIRED delay to give the servo time to move
          x = x + 1;
    }
}
//blinkNum: Used as an onboard indication that thet code has uploaded
void blinkNum(int numBlinks)  //Blinks the onboard LED (numBlinks) (3) times
{
      for (int i = 0; i < numBlinks; i++) // blinks led numBlinks times by incrementing i
      {
          digitalWrite(onboardLEDPin, HIGH);  //enables the onboardLED, turning it on
```

```
            delay(100);                       //delay before turning LED off
            digitalWrite(onboardLEDPin, LOW);   //disables the onboardLED, turning it off
            delay(50);                //delay before turning LED on again, blinking the LED
        }
}
```

Appendix 6: Material List

The materials required for prototyping the Adaptable Knee Brace include:

- Arduino Nano 33 BLE
- LSM9DS1 IMU Sensor
- Lithium Ion Battery Pack - 3.7V 6600mAh
- Wires and Connectors
- Two 12” x 20” sheet of ⅛” 6061 T6 Aluminum
- One 5” x 12” sheet of ¼” 6061 T6 Aluminum
- Straps
- Neoprene Sleeve
- Bolts
- Washers
- Nuts
- High Torque Servo Motor
- Twine
- Heat Shrink
- Mounting Tape

Appendix 7: Hazard Analysis

Table 1: Risk Assessment

Hazard	Severity	Occurrence	RPN
Hyperextension of the knee	3-5	2	6-10
	Could cause anywhere from minor irritation/injuries to cartilage/muscle tears depending on the extremity of hyperextension	Added resistive components of the hinge prevent knee from extending past tracked angles	
Resistive force stops the leg too quickly	6	6	36
	If the leg stops mid swing, the likelihood of falling is high and in elderly patients, falling can cause moderate/possibly permanent damage though bone fractures	Added resistive components of the knee increase likelihood of preventing leg extension	
Over-constriction of compressive straps	2-3	7	14-21
	Could irritate the skin and cause bruising/scapes and cuts depending on tightness of the straps	For each patient over tightening knee straps is common during proper fitting	
Lithium battery	7	1	7
	If the lithium battery explodes or catches on fire, third degree burns are common. Acidic burns can also occur	Modern day battery technology with a combination of limited current draw	
Sensor error	1-2	7	7-14
	No harm occurs due to sensor error, however it can affect the resistive forces added at incorrect times which can create some discomfort	Sensors recalibrations are common, and misreadings are also very common	

Table 2: Severity Chart

Rank	Criteria: Severity of Effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Lifelong medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Lifelong medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fractures, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay
6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay
5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulance treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulance treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

Table 3: Occurrence Chart

Rank	Probability of Occurrence
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs 1 in 50 sessions (less than one in half a month)
5	Occurs 1 in 100 sessions (less than once a month)
4	Occurs 1 in 500 sessions (less than once in half a year)
3	Occurs 1 in 1000 sessions (less than once a year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

Table 4: Severity vs. Occurrence

		Occurrence									
		1	2	3	4	5	6	7	8	9	10
Severity	1	1	2	3	4	5	6	7	8	9	10
	2	2	4	6	8	10	12	14	16	18	20
	3	3	6	9	12	15	18	21	24	27	30
	4	4	8	12	16	20	24	28	32	36	40
	5	5	10	15	20	25	30	35	40	45	50
	6	6	12	18	24	30	36	42	48	54	60
	7	7	16	21	28	35	42	49	56	63	70
	8	8	16	24	32	40	48	56	64	72	80
	9	9	18	27	36	45	54	63	72	81	90
	10	10	20	30	40	50	60	70	80	90	100

1-29: This range was chosen for the acceptable region since it encompases the very low chance of occurrence but severe and higher chance of occurrence but not severe ends of the spectrum which are acceptable for our device and keep the patient within a comfortable safety range.

30-50: Was determined to be an acceptable range as long as it is as low as reasonably possible for the specific hazard. If something falls into this range it was determined to not be too dangerous for our project.

51-100: This range was determined to be unacceptable due to the fact that anything in this range because it occurs too often for its severity for our device.

Appendix 8: Verification Protocols & Completion Reports

A. Knee Brace Size / Fit Verification Protocol [JW]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must fit the average male/female elderly patient's legs. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users. This protocol will be used to verify the specified size requirements for various users, which can be found in Appendix 1: *Size Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace design will fit the average size user (Appendix 1). This study will include the following:

1. Building four test fixtures that have the specified minimum and maximum circumferences for the upper and lower brace (thigh and calf). These parameters are defined in Appendix 1.
2. Verify the test fixture dimensions by using a series of three measurements.
3. Execute a series of measurements to evaluate the different size parameters as defined by Appendix 1.

The specifications for this protocol can be found in Appendix 1: *Size Requirements and Specifications*.

3 References

The references used for this protocol are provided in below:

1. Stallard J, Dounis E, Major RE, Rose GK. One leg swings through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980; 51(1):71-77.

4 Materials/Equipment

The test equipment used in this protocol are provided in Table 2 below:

Table 2: Equipment Overview

Equipment	Manufacturer	Model #	Expiration Date (if applicable)
Tape Measurer	N/A	N/A	N/A
Water Jet	OMAX	2626	N/A
Prototyped Knee Brace	TCNJ	N/A	N/A

The test materials used in this protocol for the test fixtures are provided in Table 3 below:

Table 3: Material Overview

Product Family	Size	Manufacturer	Model #
* Aluminum	2 inch thick		N/A

* *Note:* Aluminum was selected as a cheap and quick material for manufacturing purposes, however any material will suffice so long as it can meet the specified circumference sizes. Note if any materials / equipment deviates from this protocol and include the deviation and justification in the completion report.

Four cylindrical test fixtures will be built out of aluminum or other spare materials as applicable. They may be 1.5 inches or larger in height to accommodate for the width of the straps that will attach the brace to the fixture (2” for the thigh and 2” for the calf). The fixtures may be manufactured in the machine shop using the water jet machine or other machinery as necessary. Verify that the circumference of each test fixture meets the specified circumferences upon completion of manufacturing.

5 Methods

5.1 For each minimum and maximum circumference specification, the circumference measurements will be verified prior to strapping on the brace. The measurement for each of the test fixtures will be repeated three times to ensure accuracy in measurement recording.

5.2 After measuring the relevant test fixtures, the brace will be secured by its straps to each fixture and visually analyzed to determine if it is able to successfully secure around the fixture.

5.3 **Test Method Setup**

For the size / fit test of the brace, four test fixtures of various circumference must be manufactured. Begin by calculating the diameter for each of the following circumferences (via Appendix 1):

- 42.4 cm
- 53.6 cm
- 28.8 cm
- 35.2 cm

Record the respective diameters in Table 4 below:

Table 4: Calculated Diameters

Specified Circumference	Calculated Diameter
42.4 cm	
53.6 cm	
28.8 cm	
35.2 cm	

Using the Water Jet machine and an Aluminum plate that is at least 1.5in thick, cut out four cylinders with the diameters in the table above.

Note: If the exact size is unable to be manufactured, under size the test fixtures for minimum specs and oversize the test fixtures for maximum specs. These circumferences will be measured and recorded during testing and recorded in Appendix 2: *Data Sheets*.

5.4 **Test Method Execution**

Prior to performing the verification test, use a tape measurer to measure the circumference of each test fixture three times. Record the measurement in Appendix 2, Table 1, Trial 1.

Note: If a test fixture's measurement does not meet the required specs in measurement, the verification test fails for that spec and a new test fixture must be manufactured. If a new test fixture is not manufactured, justify why the current test fixture is able to continue being used. Reperform this protocol upon manufacturing a new fixture/justification for current test fixture.

Execute the verification test by attaching the brace by its straps to each test fixture and visually analyze if the brace succeeds or fails in securing around the test fixture.

Repeat this process for each respective brace location and test fixture.

5.5 Test Method Results

Each of the test fixture circumferences will be recorded in Appendix 2, Table 1. If the test fixture slips out during visual inspection, or other abnormalities occur, note these in Appendix 2, Table 3, and rerun the test. Record the rerun value in Appendix 2, Table 1. The test fails if the brace does not have the length to fit around the max spec test fixtures or if the brace straps are too long to secure to itself on the min spec test fixtures.

Document all recorded data in Appendix 2: *Data Sheets*.

6 Calculations Statistical Methods

Calculate the diameter for creating each test fixture by dividing the specified circumferences by pi (3.14). Record the calculated values in Table 4.

Diameter = Circumference / $\boldsymbol{\pi}$

No other calculations or statistical methods are required for this protocol; the data collected from this protocol will be analyzed as is.

Note: Statistical analysis is not required for this protocol because if a single measurement for the test fixture fails, the related spec will fail immediately; it is not based on averages. The three measurements will be used to verify that the test fixtures meet spec and remove user measurement error. Additionally, there will be no comparisons between different sizes or runs because each event is independent of one another and there is no comparison between locations, max/min, or trials.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 5: Criteria for Success

Location	Specification
Minimum Upper Brace / Thigh	Successful attachment of brace to test fixture of ≤ 42.4 cm

Maximum Upper Brace / Thigh	Successful attachment of brace to test fixture of ≥ 53.6 cm
Minimum Lower Brace / Calf	Successful attachment of brace to test fixture of ≤ 28.8 cm
Maximum Lower Brace / Calf	Successful attachment of brace to test fixture of ≥ 35.2 cm

Note: If improper size test fixtures are manufactured and noticed while performing this protocol, finish running the protocol and record the values in Appendix 2, Table 1, noting which specs passed and failed. For any specs that failed due to incorrect manufacturing of the test fixture, reperform this protocol only for those specified test fixtures, ensuring that a properly manufactured test fixture within spec is used for the new test.

8 Appendix

Appendix Number	Description
1	Size Requirements and Specifications
2	Data Sheets

APPENDIX 1: SIZE REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	1.1.1 Test fixtures for the minimum and maximum circumferences will be designed and manufactured. The upper brace will be adjusted onto the minimum and maximum circumferences of the thigh test fixtures 1.1.2 Test fixtures for the minimum and maximum circumferences will be designed and manufactured. The lower brace will be adjusted onto the minimum and maximum circumferences of the calf test fixtures

Justification: The device must be able to fit users with different body shapes / sizes within the target population of elderly patients, aged 65-90 years old. Within this population the average thigh circumference was found to deviate by 5.6 cm and the average calf circumference was found to deviate by 3.2 cm. So, the brace must be able to fit the minimum and maximum circumference for both the calf and thigh.

APPENDIX 2: DATA SHEETS

Table 1: Data Sheet

Location	Specification		Measurements				Size/Fit Visual Inspection: Pass / Fail
	Min / Max	Spec	Trial 1	Trial 2	Trial 3	Test Fixture Manufacturing	
Thigh	Minimum	≤ 42.4 cm				□ **Pass** □ **Fail**	□ **Pass** □ **Fail**
	Maximum	≥ 53.6 cm				□ **Pass** □ **Fail**	□ **Pass** □ **Fail**
Calf	Minimum	≤ 28.8 cm				□ **Pass** □ **Fail**	□ **Pass** □ **Fail**
	Maximum	≥ 35.2 cm				□ **Pass** □ **Fail**	□ **Pass** □ **Fail**

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table (Table 2) below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 3: Observations of Data Collection

Specification	Trial #	Observation

B. Knee Brace Size / Fit Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Brace Fitting/Sizing verification has been completed for the Adaptive Knee Brace located in room BME218 at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the Brace Fitting/Sizing Verification Report were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the adjustable straps meet the specified design criteria during verification testing and adheres to the approved specifications, concluding that the verification capabilities have been verified.

2 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must fit the average male/female elderly patient's legs. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users. This protocol will be used to verify the specified size requirements for various users, which can be found in Appendix 1: Size Requirements and Specifications.

3 Objectives

The report summarizes the retrospective brace fitting/sizing verification for the Adaptive Knee Brace located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification/validation report is to document the objective evidence that:

- Building four test fixtures that have the specified minimum and maximum circumferences for the upper and lower brace (thigh and calf). These parameters are defined in Appendix 1.
- Verify the test fixture dimensions by using a series of three measurements.
- Execute a series of measurements to evaluate the different size parameters as defined by Appendix 1.

4 References

The following references were used for this report:

1. Stallard J, Dounis E, Major RE, Rose GK. One leg swings through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980; 51(1):71-77.
2. Knee Brace Size/Fit- Verification Protocol

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- ⅛" 6061 T6 Aluminum brace thigh and calf wrap arounds,

- Nylon Straps with an adjustable velcro region

The equipment used to execute this protocol are provided below:

- Ruler
- Measuring tape

6 Methods

6.1 Measured and cut the straps to meet the diameter specifications in Appendix 1

6.2 After taking the measurements of the subjects used for testing an average was approximated, and used for the metal wrap arounds where 3 times the standard deviation was covered by the velcro straps.

7 Results and Analysis

As per requirement 1 the brace was designed to fit our intended user with an average thigh circumference of 48 ± 5.6 cm and a calf circumference of 32 ± 3.2 cm. Using this requirement and a sizing chart from other knee braces, a thigh circumference of 48 cm and a calf circumference of 39 cm was ideal for our intended user.

All tests met the requirements of the protocol.

8 Conclusions & Assessment of Acceptance Criteria

The Brace Fitting/ Sizing verification has been established by objective evidence that all key aspects of the Adaptive Knee Brace adheres to the approved specifications.

The Brace Fitting/ Sizing verification has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 1).

9 Appendices

Appendix Number	Title
1	Design Inputs

APPENDIX 1: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

C. Knee Brace Load Capacity Verification Protocol [JW]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must be able to support the average weight of male / female elderly patients (72kg). Additionally, the brace must be able to support at least 3 times the average elederly male's weight to account for various user interfaces and activities while using the device (i.e. carrying additional load, jumping, running). This protocol will be used to verify the specifications for this load requirement, which can be found in Appendix 1: *Load Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace design will be capable of bearing the load from the average elderly user (Appendix 1). This study will include the following:

1. FEA simulations that perform load tests at 72kg and at 216kg
2. User interface with the brace while performing activities that create loads on the brace that are ≥ 72kg
3. Analysis for both FEA and the user interface tests to verify that the brace design meets the specifications

3 References

The references used for this protocol are provided in below:

1. Lee, H., Ha, D., Kang, Y. S., & Park, H. S. (2016). Biomechanical Analysis of the Effects of Bilateral Hinged Knee Bracing. Frontiers in bioengineering and biotechnology, 4, 50.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Computer with a FEA Software
- The Adaptable Knee Brace
- Scale
    - The user must be able to stand on the scale and the scale must be capable of reading within the acceptance criteria weight ranges

The test materials required for this protocol are provided below:

- 45lb weights
- Other size weights as needed
    - If other size weights are used, include them in the completion report

Note: If any materials / equipment deviates from this protocol, include the deviation and justification in the completion report.

5 Methods

5.1 FEA Load Test

5.1.1 Save Solidworks 3 dimensional brace file as an ".igs" file.

5.1.2 Open the ".igs" brace file in SpaceClaim and save it as a ".scdoc".

5.1.3 Import the ".scdoc" file in Ansys workbench.

5.1.4 Create a new Rigid dynamics analysis system.

5.1.5 Delete automatically generated part contacts, create a new contacts folder and use the automatically generated joints function (This can be found by right clicking on the folder) to automatically generate joint connections. Once joints are generated click through all of the generated joints to assure they have been properly generated.

5.1.6 Add forces from the top and bottom parts of the brace equal to a 72kg person jumping from a 1 meter height. (F = 705.6N)

5.1.7 Assign brace supports to the two pins which attach the upper and lower braces to the double hinge mechanism.

5.1.8 Add tests for deformation, shear, and normal stress to the model.

5.1.9 Click the “Solve” button to run the analysis of the model.

5.1.10 Open each test and take screenshots of the result.

5.1.11 Repeat steps 5.1.5 through 5.1.9 for 216kg (about 477lbs or F = 2116.8).

5.2 User Interface Load Test

5.2.1 Place the brace on the scale and zero the scale so it reads about zero.

5.2.2 Place the brace on the knee and strap it around the leg until a comfortable, but tight, fit is achieved.

5.2.3 With the brace on, stand on the zero’d scale and record the weight of the user in the data sheets (Appendix 2 Table 1)

5.2.4 If applicable, while remaining on the scale, have someone hand appropriate size weights to you until the 72kg (about 159lbs) criteria is met. Record the scale reading in the data sheets (Appendix 2 Table 1).

5.2.5 Visually inspect the brace. Record any damage to the brace in Appendix 2 Table 3.

5.2.6 Repeat 3 times per user, with 2 different users.

6 Calculations Statistical Methods

No calculations or statistical analysis is required for this protocol since the weight applied is a reference weight. The actual test is a visual inspection to determine if any damage is reflected on the brace or not.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test	Specification	
FEA Load Test	≥ 72kg	≥ 216kg
User Interface Load Test	≥ 72kg	

The above criteria for success must be met with no damage to the knee brace. If damage is found on the knee brace due to weights < 72kg or < 216kg, then the test fails. If no damage is found, that test passes. All tests must pass for each set of trials for the brace to pass this protocol.

***** *Note:* If any damage occurs to the brace during user interface testing, it must be noted in the completion report and a justification must be made on whether it passes/fails the test (if it meets the specification). If the damage limits the brace's ability to perform its main requirements (Appendix 3: *Design Inputs*), the test fails.

8 Appendix

Appendix Number	Description
1	Load Requirements and Specifications
2	Data Sheets

APPENDIX 1: LOAD REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
2. The device must be able to support the weight of the target population (men and women ages 65+)	2.1 The device must be wearable by men and women with an average body weight of ~72 kg for men. 2.2 As a factor of safety. the device must be able to withstand forces of ≥ 3 times the average male body weight (216kg)	2.2.1 The brace design will be simulated in a FEA environment using forces of the average male body weight verifying that the device can withstand ≥ 72kg and ≥ 216kg 2.2.2 The device user will perform strenuous activities which provide high forces to the knee joints, such as jumping, to verify that the brace can withstand ≥ 72kg and ≥ 216kg

Justification: The device must be able to support the weight of the user with additional factors of safety designed into the device to allow the brace to support the user's weight during various activities. Since men have a higher average weight compared to women, only the weight for men will be verified since it is the maximum spec.

APPENDIX 2: DATA SHEETS

Table 1: Data Sheet

Test Type	72kg Test Actual Weight Used	216kg Test Actual Weight Used	User Weight
FEA Load Test			
FEA Load Test			
User Interface Load Test			

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table (Table 2) below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 3: Observations

Specification	Trial #	Observation

D. Knee Brace Load Capacity Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

The load capacity verification has been completed for the mechanical knee brace in Ansys Workbench at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the Knee Brace Load Capacity -Verification Protocol - were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the mechanical portions of the knee brace are able to withstand the forces under normal intended use (705.6N) along with forces up to three times that (2116.8N) and adheres to the approved specifications, concluding that the verification activity capabilities have been verified.

2 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must be able to support the average weight of male / female elderly patients (72kg). Additionally, the brace must be able to support at least 3 times the average elederly male's weight to account for various user interfaces and activities while using the device (i.e. carrying additional load, jumping, running). This protocol will be used to verify the specifications for this load requirement, which can be found in Appendix 2: *Load Requirements and Specifications*.

3 Objectives

The objective of this protocol is to verify that the knee brace design will be capable of bearing the load from the average elderly user (Appendix 2). The study concluded the following:

- FEA simulations that were perform load tested the brace at 72kg and at 216kg
- Analysis for both FEA and the user interface tests verified that the brace design meets the specifications

4 References

The following references were used for this report:

1. Herng-Chia Chiu, Hsing-Yi Chang, Lih-Wen Mau, Ti-Kai Lee, Hong-Wen Liu, Height, Weight, and Body Mass Index of Elderly Persons in Taiwan, The Journals of Gerontology: Series A, Volume 55, Issue 11, 1 November 2000, Pages M684–M690
2. Stallard J, Dounis E, Major RE, Rose GK. One leg swing through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 198

5 Materials/Equipment

The test equipment required for this protocol are provided below:

- Computer with a FEA Software
- The Adaptable Knee Brace
- Scale

    - The user must be able to stand on the scale and the scale must be capable of reading within the acceptance criteria weight ranges

The The test materials required for this protocol are provided below:

- 45lb weights
- Other size weights as needed
    - If other size weights are used, include them in the completion report

6 Methods

6.1 **FEA Load Test**

6.1.1 The Solidworks 3 dimensional brace file was saved as an ".igs" file.

6.1.2 The ".igs" brace file was opened in SpaceClaim and saved as a ".scdoc".

6.1.3 The ".scdoc" file was imported into Ansys workbench.

6.1.4 A rigid dynamics analysis system was created.

6.1.5 Automatically generated part contacts were deleted, a new contacts folder was created and use the automatically generated joints function (This can be found by right clicking on the folder) was used to automatically generate joint connections. Once the joints were generated all of the generated joints were inspected to assure they had been properly generated.

6.1.6 Forces from the top and bottom parts of the brace were added equal to a 72kg person jumping from a 1 meter height. (F = 705.6N)

6.1.7 The two pins which attach the upper and lower braces to the double hinge mechanism were assigned as supports

6.1.8 Tests for deformation, shear, and normal stress to the model were added.

6.1.9 The Analysis' were run.

6.1.10 Screenshots were taken of all results.

6.1.11 Steps 6.1.5 through 6.1.9 were repeated for 216kg (about 477lbs or F = 2116.8).

6.2 **User Interface Load Test**

6.2.1 The brace was placed on the scale and zero the scale so it reads about zero.

6.2.2 The brace was placed on the knee and strapped around the leg until a comfortable, but tight, fit was achieved.

6.2.3 With the brace on, the scale was zero'd and the weight of the user was recorded in the data sheets (Appendix 2 Table 1)

6.2.4 The brace was visually inspected for damage and any damage was recorded

6.2.5 This was repeated 3 times per user, with 2 different users.

7 Results and Analysis

All resulting forces from the figures in Appendix 1 were obtained and compared to the material properties of the 6061-T6 Aluminum and 316 Stainless Steel. The maximum force from the three times average force experiment was a normal force of 4.62MPa and a maximum shear force of 3.27MPa. These values were then compared to the yield stresses of the materials, 276MPa for the 6061-T6 Aluminum and 215MPa for the 316 Stainless Steel. It was determined from this that the material properties of both materials were significantly higher than necessary for this application and therefore all requirements for this protocol were met in these tests.

8 Conclusions & Assessment of Acceptance Criteria

The load capacity protocol has been established by objective evidence that all key aspects of the mechanical portions of the knee brace adheres to the approved specifications.

The load capacity protocol has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 2).

9 Appendices

Appendix Number	Title
1	Raw Data Sheets
2	Design Inputs

APPENDIX 1: RAW DATA SHEETS

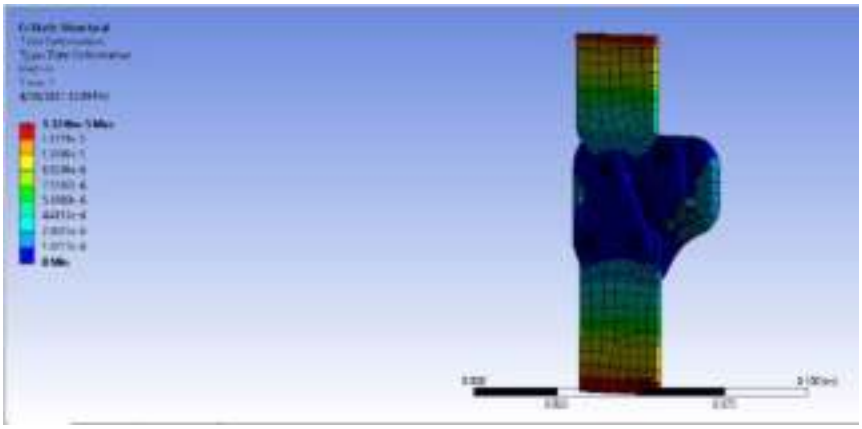


Figure 1. This figure shows the deformation of the hinge design during normal loading. The results showed a maximum of 13.2µm

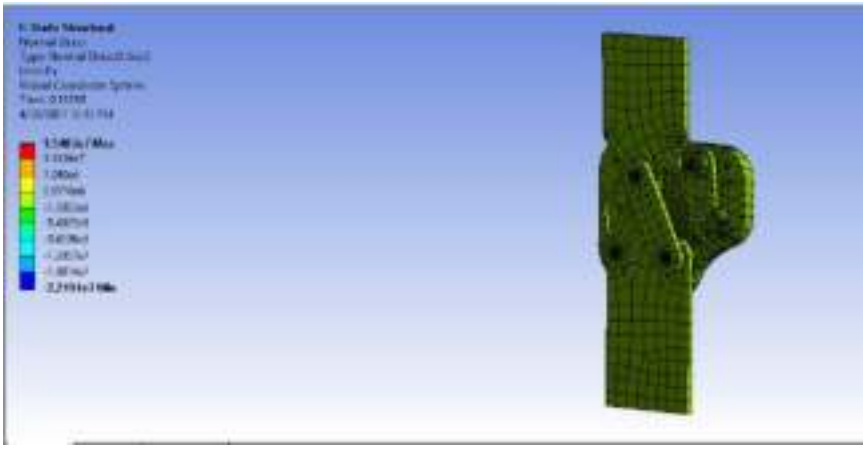


Figure 2. This figure shows the results of normal stress on the hinge design during normal loading. A maximum of 1.54MPa was seen in the calf portion of the brace.

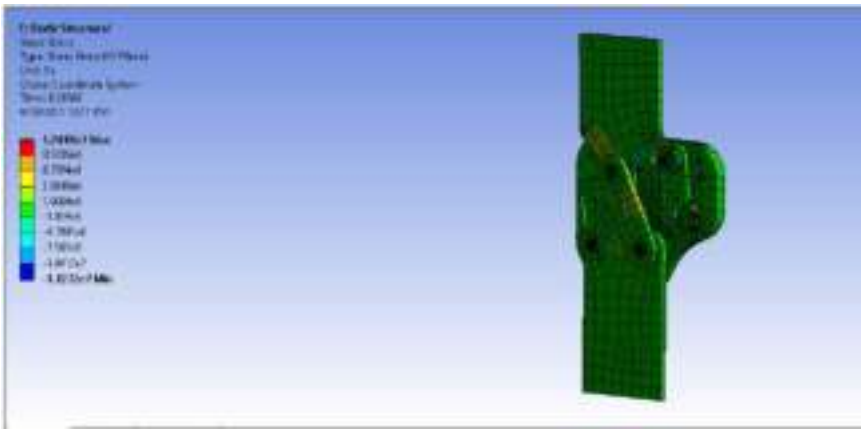


Figure 3.This figure shows the results of the shear stress of the hinge during normal loading. The maximum shear stress was on the pins holding together the hinge mechanism which had a force of 1.24MPa.

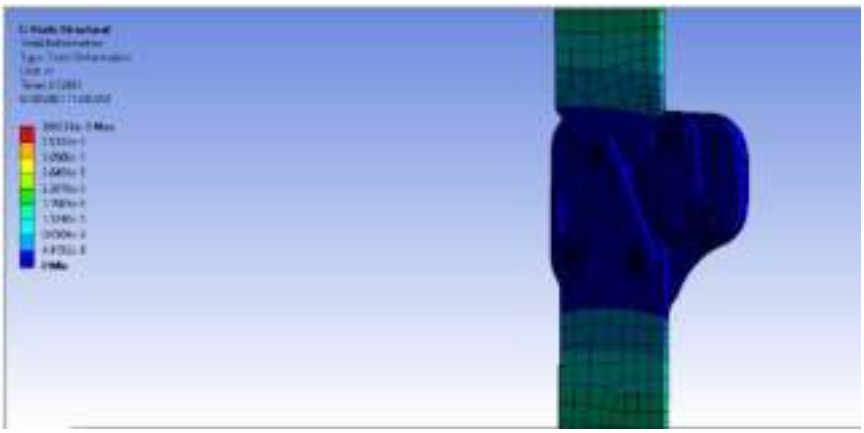


Figure 4. This figure shows the deformation of the hinge design during normal loading. The results showed a maximum of 39.8µm

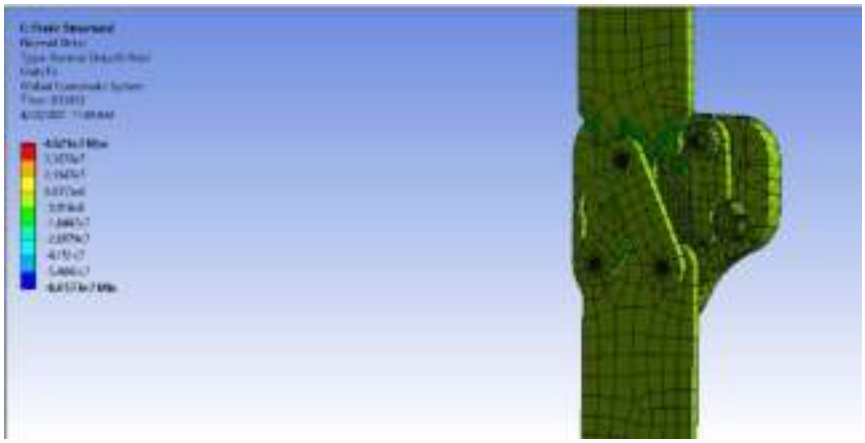


Figure 5. This figure shows the results of normal stress on the hinge design during normal loading. A maximum of 4.62MPa was seen in the calf portion of the brace.

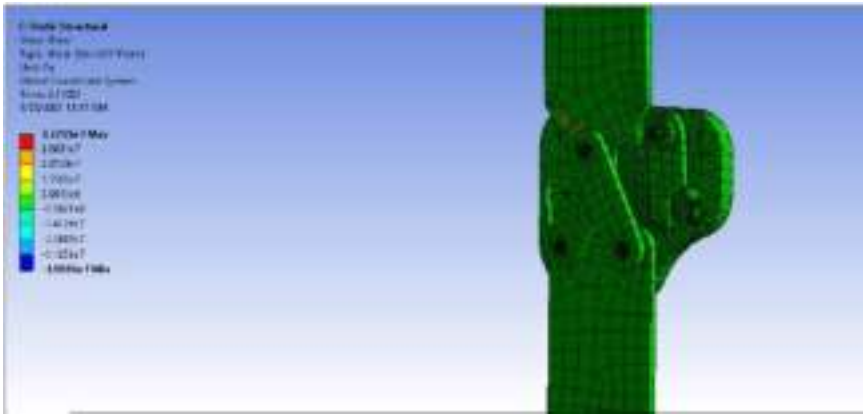


Figure 6. This figure shows the results of the shear stress of the hinge during normal loading. The maximum shear stress was on the pins holding together the hinge mechanism which had a force of 3.27MPa.

APPENDIX 2: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

E. Knee Brace Hyperextension Prevention Verification Protocol [JW & AlC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must prevent hyperextension of the knee. The knee brace hinge has a stopper that mechanically restricts the motion of the brace past vertical alignment. This protocol will be used to verify that the knee brace can restrict motion below an angle of 0° ± 3°, thus preventing knee hyperextension which commonly occurs past this angle. The specifications for this requirement can be found in Appendix 1: *Hyperextension Prevention Requirements and Specifications.*

2 Objectives

The objective of this protocol is to verify that the knee brace design does not cause hyperextension of the knee (Appendix 1). This study will include the following:

1. Verification that the knee brace will not extend past an angle of 0° ± 3° at any point in the gait cycle

3 References

The references used for this protocol are provided in below:

1. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020

4 Materials/Equipment

The test equipment used in this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Joint Angle Computation
- The Adaptable Knee Brace

There are no required test materials for this protocol.

5 Methods

5.1 The brace is mechanically restricted to prevent hyperextension past 0°

5.2 With the brace unattached from any operator, test the range of motion of the brace by extending the brace and using a protractor to measure maximum angle of brace hyperextension.

5.3 Once the brace is attached to the subject also take measurements of the angle using the magnetometer attached to the microcontroller.

Document all recorded data in Appendix 2: *Data Sheets*.

6 Calculations Statistical Methods

The average minimum and maximum angles can be found using the following equation:

$$\text{Average Angle} = (\text{Sum of Trials 1-3 Angles}) / 3$$

No statistical analysis is required since the angle measurements are independent of the user and environmental effects.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test	Specification
Brace Angle	$\geq 0° \pm 3°$

8 Appendix

Appendix Number	Description
1	Hyperextension Prevention Requirements and Specifications
2	Data Sheets

APPENDIX 1: HYPEREXTENSION PREVENTION REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation

Justification: The device must be able to measure angles of the knee or else the device may put the user at risk of potential harm during gait assistance.

APPENDIX 2: DATA SHEETS

Table 1: Data Sheet

Min/Max Angle	Measured Value - Trial 1	Measured Value - Trial 2	Measured Value - Trial 3	Measured Value - Average
Maximum Brace Angle				
Minimum Brace Angle				

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table (Table 2) below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 3: Observations of Data Collection

Specification	Trial #	Observation

F. Knee Brace Hyperextension Prevention Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Hyperextension prevention verification has been completed as per Requirement 3.

The verification acceptance criteria defined in the Knee Brace Hyperextension Prevention Verification Protocol were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the brace provides a mechanical stop inhibiting the user from hyperextending their knee, concluding that the verification activity capabilities have been verified.

2 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must prevent hyperextension of the knee. The knee brace hinge has a stopper that mechanically restricts the motion of the brace past vertical alignment. This protocol will be used to verify that the knee brace can restrict motion below an angle of 0° ± 3°, thus preventing knee hyperextension which commonly occurs past this angle. The specifications for this requirement can be found in Appendix 1: Hyperextension Prevention Requirements and Specifications.

3 Objectives

The objective of this protocol is to verify that the knee brace design does not cause hyperextension of the knee (Appendix 1). This study will include the following:

- Verification that the knee brace will not extend past an angle of 0° ± 3° at any point in the gait cycle

4 References

The references used for this protocol are provided in below:

Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020

5 Materials/Equipment

The test equipment used in this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Joint Angle Computation
- The Adaptable Knee Brace

There are no required test materials for this protocol.

6 Methods

6.1 The brace is mechanically restricted to prevent hyperextension past 0°

6.2 With the brace unattached from any operator, the range of motion was tested by extending the brace and a protractor was used to measure maximum angle of brace.

6.3 Once the brace was attached to the subject measurements of the angle were taken using the magnetometer attached to the microcontroller.

7 Results and Analysis

The mechanical resistance of the brace was tested three times resulting in a maximum hyperextension of 2° which was within the required 0±3° of the requirement which led to all requirements being met.

8 Conclusions & Assessment of Acceptance Criteria

The hyperextension prevention protocol has been established by objective evidence that the hyperextension of the hinge mechanism adheres to the approved specifications.

The hyperextension prevention protocol has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 1).

9 Appendices

Appendix Number	Title
1	Design Inputs

APPENDIX 1: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.

2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to sampling rate of 300Hz	Ammeter to probe system to test amperage of circuit
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage

9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

G. Hinge Motion Verification Protocol [JW]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must allow minor vertical motion and major rotational motion of the knee. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users. The hinge is located directly next to the knee flexion point to reduce pain and side effects commonly caused by misaligned brace hinges. The hinge includes a stopper that restricts the rotational motion of the knee while also allowing minor vertical motions of the knee (commonly seen during impact activities). This protocol will be used to verify the specified hinge motions for various users. The requirements and specifications can be found in Appendix 1: *Hinge Motion Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace design will allow both vertical and rotational motion around the knee (Appendix 1). This study will include the following:

1. A compression test to verify that the hinge allows the brace to compress up to 2mm
2. A rotational test to verify that the hinge allows the brace to rotate between a minimum spec of 0° to 60°

3 References

The references used for this protocol are provided in below:

1. Lee, H., Ha, D., Kang, Y. S., & Park, H. S. (2016). Biomechanical Analysis of the Effects of Bilateral Hinged Knee Bracing. Frontiers in bioengineering and biotechnology, 4, 50.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Accelerometer
- Gyroscope
- Joint Angle Computation
- The Adaptable Knee Brace

There are no test materials required for this protocol.

5 Methods

5.1 Compression Test

5.1.1 Attach the brace securely to an operator's knee, ensuring minimal/no movement of the brace once secured.

5.1.2 `Attach the accelerometer to the brace hinge so that any movements of the hinge can be measured.

5.1.3 While recording on the accelerometer, have the operator jump about 6 inches off the ground. Then repeat while having the operator jump about 12 inches off the ground.

5.1.4 Record the vertical displacement values of the brace upon impact for both the 6 inch jumps and the 12 inch jumps. Record the values in Appendix 2.

5.1.5 Repeat the test 3 times per jump height per operator, for 2 different 2 operators.

5.3 Rotation Test

5.3.1 Set up the Adaptable Knee Brace so it is not attached to any operator.

5.3.2 Attach the gyroscope and the joint angle computation to the brace hinge so the angle of the brace can be recorded.

5.3.3 Manually rotate the brace to the minimum and maximum allowable angles and record the angle measurements in Appendix 2.

5.3.4 Repeat 3 times.

Document all recorded data in Appendix 2: *Data Sheets*.

6 Calculations Statistical Methods

The average angle and the average displacement can be calculated using the following:

$$\text{Average} = \text{Sum of All Trials} / \#\ \text{of Trials}$$

For the compression test, run an ANOVA with a post hoc Tukey test to determine if there are any significant differences between the hinge displacements for the 6 inch and 12 inch jump heights.

For the rotation test, no statistical analysis is required.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test	Specifications
Vertical Movement	$0\text{mm} \leq x \leq 2\text{mm}$
Rotation Range	$0° < x < 60°$

8 Appendix

Appendix Number	Description
1	Hinge Motion Requirements and Specifications
2	Data Sheets

APPENDIX 1: HINGE MOTION REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	The device will go through a series of physical tests to measure and record the displacement and range of angles for the brace.

Justification: Vertical movement of the joints during sudden high forces is important for avoiding increased strain on the knee joint. Rotational motion allows for proper joint motion and allows for the patient to better perform gait rehabilitation.

APPENDIX 2: DATA SHEETS

Table 1: Data Sheet

Test	Test Measurement	Measured Value - Trial 1	Measured Value - Trial 2	Measured Value - Trial 3	Measured Value - Average
Compression Test - Operator 1	6 inch jump				
	12 inch jump				
Compression Test - Operator 2	6 inch jump				
	12 inch jump				
Rotation Test	Minimum Angle				
	Maximum Angle				

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table (Table 2) below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 3: Observations of Data Collection

Specification	Trial #	Observation

H. Hinge Motion Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Hinge motion verification protocol has been completed for the hinge portion or the brace located in room STEM 107 at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the requirement 4 were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the hinge mechanism can apply rotational restriction and adheres to the approved specifications, concluding that the hinge motion capabilities have been verified.

2 Introduction/Background

The hinge is located directly next to the knee flexion point to reduce pain and side effects commonly caused by misaligned brace hinges. The hinge includes a stopper that restricts the rotational motion of the knee while also allowing minor vertical motions of the knee (commonly seen during impact activities). This protocol will be used to verify the specified hinge motions for various users. The requirements and specifications can be found in Appendix 1: *Hinge Motion Requirements and Specifications*.

3 Objectives

The objective of this protocol is to verify that the knee brace design will allow both vertical and rotational motion around the knee (Appendix 1). This study will include the following:

- A compression test to verify that the hinge allows the brace to compress up to 2mm
- A rotational test to verify that the hinge allows the brace to rotate between a minimum spec of 0° to 60°

4 References

The references used for this protocol are provided in below:

1. Lee, H., Ha, D., Kang, Y. S., & Park, H. S. (2016). Biomechanical Analysis of the Effects of Bilateral Hinged Knee Bracing. Frontiers in bioengineering and biotechnology, 4, 50.

5 Materials/Equipment

The test equipment required for this protocol are provided below:

- Accelerometer
- Gyroscope
- Joint Angle Computation
- The Adaptable Knee Brace

There are no test materials required for this protocol.

- Protractor

6 Methods

6.1 **Rotation Test**

6.1.1 The Adaptable Knee Brace was set up so that it is not attached to any operator.

6.1.2 The gyroscope and the joint angle computation were used to determine the angle of the brace along with a protractor.

6.1.3 The brace was manually rotated to the minimum and maximum allowable angles and the angle measurements were recorded

6.1.4 This was then repeated for a total of three times.

7 Results and Analysis

A range of motion of 2-88° was allowed with no added restriction added to the brace which was recorded using the electronics and confirmed using a protractor.

8 Conclusions & Assessment of Acceptance Criteria

The hinge motion protocol has been established by objective evidence that all key aspects of the hinge mechanism adheres to the approved specifications.

The hinge motion has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 1).

9 Appendices

Appendix Number	Title
1	Design Inputs

APPENDIX 1: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

I. Microcontroller Verification Protocol [JW & AlC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the device must operate with very low latency. Operating with low latency is important so real time data can be retrieved and used to calculate an applied force in real time. With poor latency speeds, this will greatly reduce the effectiveness of the Adaptable Knee Brace, and may even lead to harm for the operator. This protocol will be used to verify the specified microcontroller latency requirements, which can be found in Appendix 1: *Microcontroller Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace microcontroller latency is fast enough for responsive brace assistance (Appendix 1). This study will include the following:

1. Preliminary equipment testing
2. Circuit connection for IC2 communication
3. Test code for data sampling and data rates

3 References

The references used for this protocol are provided in below:

1. Fast, Flexible Closed-Loop Feedback: Tracking Movement in “Real-Millisecond-Time”, Keisuke Sehara, Viktor Bahr, Ben Mitchinson, Martin J. Pearson, Matthew E. Larkum, Robert N. S. Sachdev, eNeuro 14 October 2019, 6 (6) ENEURO.0147-19.2019
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augmented, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.). https://store.arduino.cc/usa/nano-33-ble.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Arduino IDE software v1.8.13

No test materials are required for this protocol.

5 Methods

5.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

5.2 Attach the microcontroller to the laptop using a micro USB cable for uploading code and serial communication.

5.3 Download and launch the Arduino IDC software v1.8.13 on the laptop. Compile and upload the test code for testing the on board inertial sensors for sampling rate.

5.4 Run the code and opened the serial monitor to read the sampling rate for each sensor (accelerometer, gyroscope, magnetometer)

5.5 Run the code three times for three trials and compile the results of the three tests in Appendix 3, Table 1: Sampling Rate Test for Accelerometer, Gyroscope and Magnetometer.

Document all recorded data in Appendix 3: *Data Sheets*.

6 Calculations Statistical Methods

The sample rate is found using the micros function in arduino. This function counts the microseconds since the board started running a program. The micros function is initialized in the sampling rate function in the Arduino library for the sensors. This function measures how long it takes to take a sample using the micros function and then converts that into the sampling rate in hertz.

$$\text{Sampling Rate} = 1/T$$

Where T is found by initializing micros = start, sampling x, y, and z data from the microcontroller, then setting micros = end, and therefore

$$T = (end - start)/10^6$$

The average sampling rate can be found using the following equation:

Average Sampling Rate = (Sum of Trials 1-3 Sampling Rate) / 3

No statistical analysis is required since the angle measurements are independent of the user and environmental effects.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test Parameter	Specification
Latency	< 10ms
Sampling Rate	≥ 300 Hz

8 Appendices

Appendix Number	Description
1	Microcontroller Requirements and Specifications
2	Reference Data Tables
3	Data Sheets
4	Code

APPENDIX 1: MICROCONTROLLER REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to sampling rate of 300Hz	Calculations based on microcontroller processing speed and sensor sampling rate

Justification: For any feedback of the actuator the sensor and latency are limited to allow response time. The device must operate at 10mA to avoid potential electrical problems while having a significantly lower risk of injury in reference to shock hazards (at worst a minor shock may be perceived).

APPENDIX 2: REFERENCE DATA TABLES

Table 1: Sensor Sampling Rate at Different Modes

Mode	Accel Sample Rate	Gyro Sample Rate	Mag Sample Rate
0	off	off	0.625 Hz
1	14.9 Hz	14.9 Hz	1.25 Hz
2	59.5 Hz	59.5 Hz	2.5 Hz
3	119 Hz	119 Hz	5 Hz
4	238 Hz	238 Hz	10 Hz
5	476 Hz	476 Hz	20 Hz
6	952 Hz	952 Hz	40 Hz
7			80 Hz
8			400 Hz

“The LSM9DS1 includes an I2C serial bus interface supporting standard and fast mode (100 kHz and 400 kHz) and an SPI serial standard interface.“

APPENDIX 3: DATA SHEETS

Table 1: Sampling Rate Test for Accelerometer, Gyroscope and Magnetometer

Sample Rate (Hz) **LSM9DS1**	**Trial 1**	**Trial 2**	**Trial 3**	**Avg**
Accelerometer				
Gyroscope				
Magnetometer				

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table 2 below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviation Table

Number	**Initials**	**Date**	**Correct Value**	**Justification**

Table 3: Observations of Data Collection

Specification	**Trial #**	**Observation**

J. Microcontroller Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Microcontroller Sampling Rate Verification has been completed for the Arduino Nano 33 BLE Microcontroller located in room BME 218 at The College of New Jersey, Ewing, NJ.

The Microcontroller Sampling Rate Verification acceptance criteria defined in the Microcontroller protocol were not satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the Arduino Nano 33 BLE Microcontroller adheres to the approved specifications, but in the final design the specifications were not met, concluding that the Microcontroller Sampling Rate capabilities were not verified.

2 Introduction/Background

The Microcontroller Sampling Rate Verification relates to the Arduino Nano 33 BLE Microcontroller located in room BME 218 at The College of New Jersey, Ewing, NJ.

The requirement for this verification/validation activity is due to new device lifecycle management (design control).

The Arduino Nano 33 BLE Microcontroller is used to control the data collection and servo adjustments of the brace.

3 Objectives

The report summarizes the retrospective Microcontroller Sampling Rate Verification for the Arduino Nano 33 BLE Microcontroller located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification/validation report is to document the objective evidence that:

- The objective of this protocol is to verify that the knee brace microcontroller latency is fast enough for responsive brace assistance.

4 References

The following references were used for this report:

1. Fast, Flexible Closed-Loop Feedback: Tracking Movement in "Real-Millisecond-Time", Keisuke Sehara, Viktor Bahr, Ben Mitchinson, Martin J. Pearson, Matthew E. Larkum, Robert N. S. Sachdev, eNeuro 14 October 2019, 6 (6) ENEURO.0147-19.2019
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augmented, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.). https://store.arduino.cc/usa/nano-33-ble.

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- No test materials are required for this verification.

The equipment used to execute this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Arduino IDE software v1.8.13

6 Methods

6.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

6.2 Attach the microcontroller to the laptop using a micro USB cable for uploading code and serial communication.

6.3 Download and launch the Arduino IDC software v1.8.13 on the laptop. Compile and upload the test code for testing the on board inertial sensors for sampling rate.

6.4 Run the code and opened the serial monitor to read the sampling rate for each sensor (accelerometer, gyroscope, magnetometer)

6.5 Run the code three times for three trials and compile the results of the three tests in Appendix 3, Table 1: Sampling Rate Test for Accelerometer, Gyroscope and Magnetometer.

7 Results and Analysis

The sample rate is found using the micros function in arduino. This function counts the microseconds since the board started running a program. The micros function is initialized in the sampling rate function in the Arduino library for the sensors. This function measures how long it takes to take a sample using the micros function and then converts that into the sampling rate in hertz.

$$\text{Sampling Rate} = 1/T$$

Where T is found by initializing micros = start, sampling x, y, and z data from the microcontroller, then setting micros = end, and therefore

$$T = (\text{end} - \text{start})/10^6$$

The average sampling rate can be found using the following equation:

$$\text{Average Sampling Rate} = (\text{Sum of Trials 1-3 Sampling Rate}) / 3$$

<can likely copy and paste from protocol but insert ACTUAL CALCULATIONS made as a reference>
<Include tables and charts as needed>
<conclude significance>
All tests met the requirements of the verification, however in the completed design the measured sampling rate was 104Hz which fails the verification.

8 Conclusions & Assessment of Acceptance Criteria

The Microcontroller Sampling Rate Verification has been established by objective evidence that all key aspects of the Arduino Nano 33 BLE adheres to the approved specifications, however the final design does not.

The Microcontroller Sampling Rate Verification has not met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 2).

9 Appendices

Appendix Number	Title
1	Reference Sheets
2	Raw Data Sheets
3	Design Inputs

APPENDIX 1: REFERENCE SHEETS

Table 1: Sensor Sampling Rate at Different Modes

Mode	Accel Sample Rate	Gyro Sample Rate	Mag Sample Rate
0	off	off	0.625 Hz
1	14.9 Hz	14.9 Hz	1.25 Hz
2	59.5 Hz	59.5 Hz	2.5 Hz
3	119 Hz	119 Hz	5 Hz
4	238 Hz	238 Hz	10 Hz
5	476 Hz	476 Hz	20 Hz
6	952 Hz	952 Hz	40 Hz
7			80 Hz
8			400 Hz

APPENDIX 2: RAW DATA SHEETS

Data Sheet Value	Measured Avg (Hz)	Percent Error
476	463.04	2.72
476	462.94	2.74
400	420.81	5.20

APPENDIX 3: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

K. Current Withdraw Verification Protocol [JW & AlC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must operate with a low current withdrawal. This is due to safety concerns so no electrical hazards are presented to the operator. This protocol will be used to verify the specified current withdrawal requirements for various users, which can be found in Appendix 1: *Current Withdraw Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace current withdrawal will be within the acceptable range (Appendix 1). This study will include the following:

1. Preliminary equipment testing

3 References

The references used for this protocol are provided in below:

1. Fast, Flexible Closed-Loop Feedback: Tracking Movement in “Real-Millisecond-Time”, Keisuke Sehara, Viktor Bahr, Ben Mitchinson, Martin J. Pearson, Matthew E. Larkum, Robert N. S. Sachdev, eNeuro 14 October 2019, 6 (6) ENEURO.0147-19.2019
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augmented, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.). https://store.arduino.cc/usa/nano-33-ble.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires

- Arduino IDE software v1.8.13
- Digital Multimeter

No test materials are required for this protocol.

5 Methods

5.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

5.2 To measure the voltage output at the 3.3V and Vin pins of the Arduino Nano 33 BLE microcontroller connect the microcontroller to a laptop using a micro USB cable.

5.3 Connect the positive voltage port of a digital multimeter to 3.3V voltage pin and the COM port of the multimeter to the ground pin of the microcontroller. The circuit schematic for these connections can be found in Appendix 2. This measures the voltage output at the 3.3V voltage pin.

5.4 Connect the positive voltage port of a digital multimeter to Vin voltage pin and the COM port of the multimeter to the ground pin of the microcontroller. The circuit schematic for these connections can be found in Appendix 2. This measures the voltage output at the Vin voltage pin.

5.4 Disconnect the multimeter and micro USB. Connect the positive terminal of the battery to the 3.3V voltage pin on the microcontroller. Then connect the ground of the microcontroller to the Amp meter port of the multimeter. Then connect the COM port of the multimeter to the negative terminal on the battery to complete the circuit. The circuit schematic for these connections can be found in Appendix 2. This measures the current drawn front the microcontroller.

5.5 Compile the results from each measurement in Appendix 4, Table 1: Current and Voltage Measured.

Document all recorded data in Appendix 4: *Data Sheets*.

6 Calculations Statistical Methods

No calculations or statistical analysis is required since the angle measurements are independent of the user and environmental effects.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test Parameter	Specification
Current Withdraw from external power source	≤ 10 mA

8 Appendices

Appendix Number	Description
1	Current Withdraw Requirements and Specifications
2	Circuit Schematics
3	Reference Data Sheets
4	Data Sheets

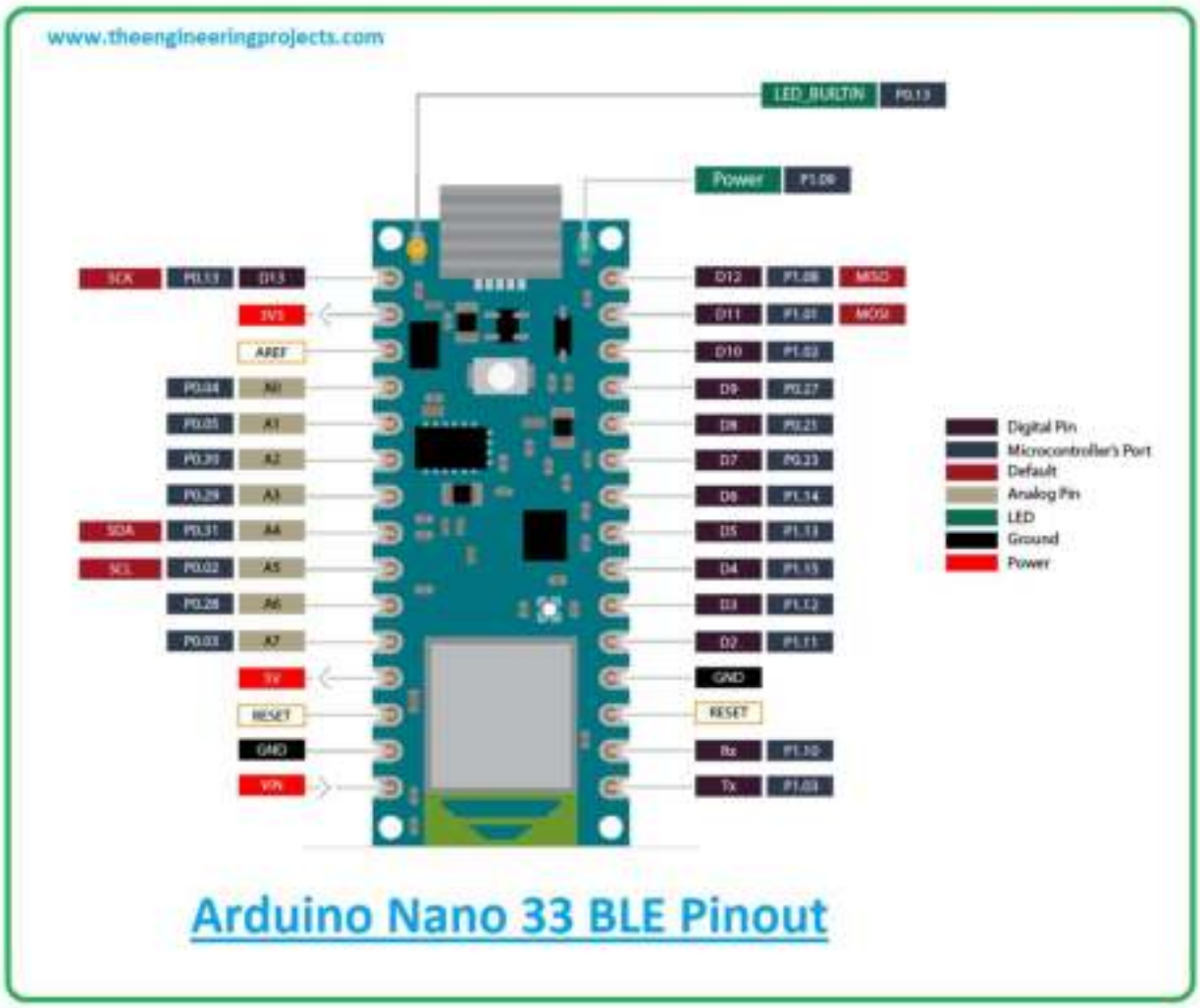
APPENDIX 1: CURRENT WITHDRAW REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	Ammeter to probe system to test amperage of circuit

Justification: For any feedback of the actuator the sensor and latency are limited to allow response time. The device must operate at 10mA to avoid potential electrical problems while having a significantly lower risk of injury in reference to shock hazards (at worst a minor shock may be perceived).

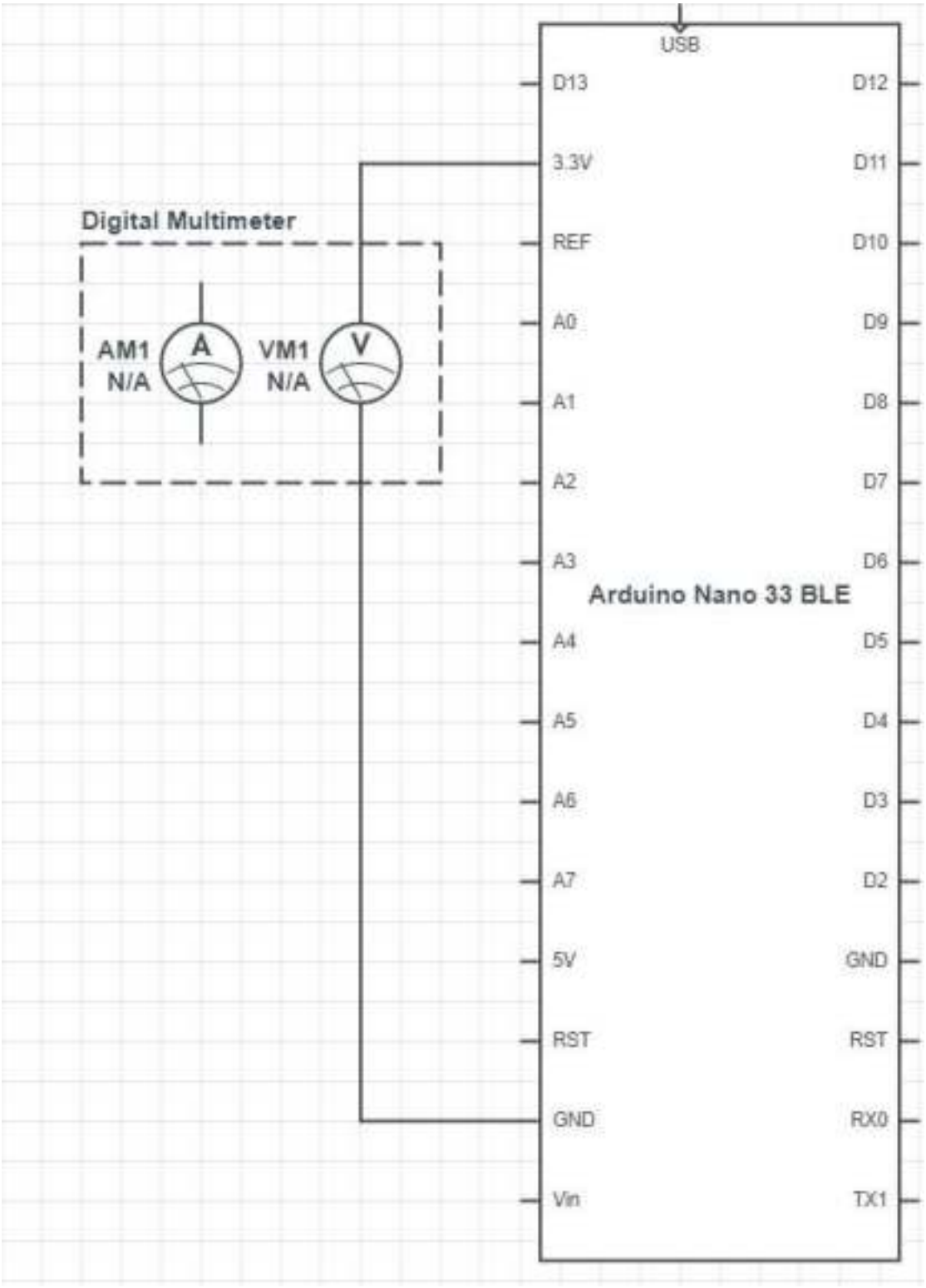
APPENDIX 2: CIRCUIT SCHEMATICS

Schematic 1: Arduino Nano 33 BLE Microcontroller Pinout

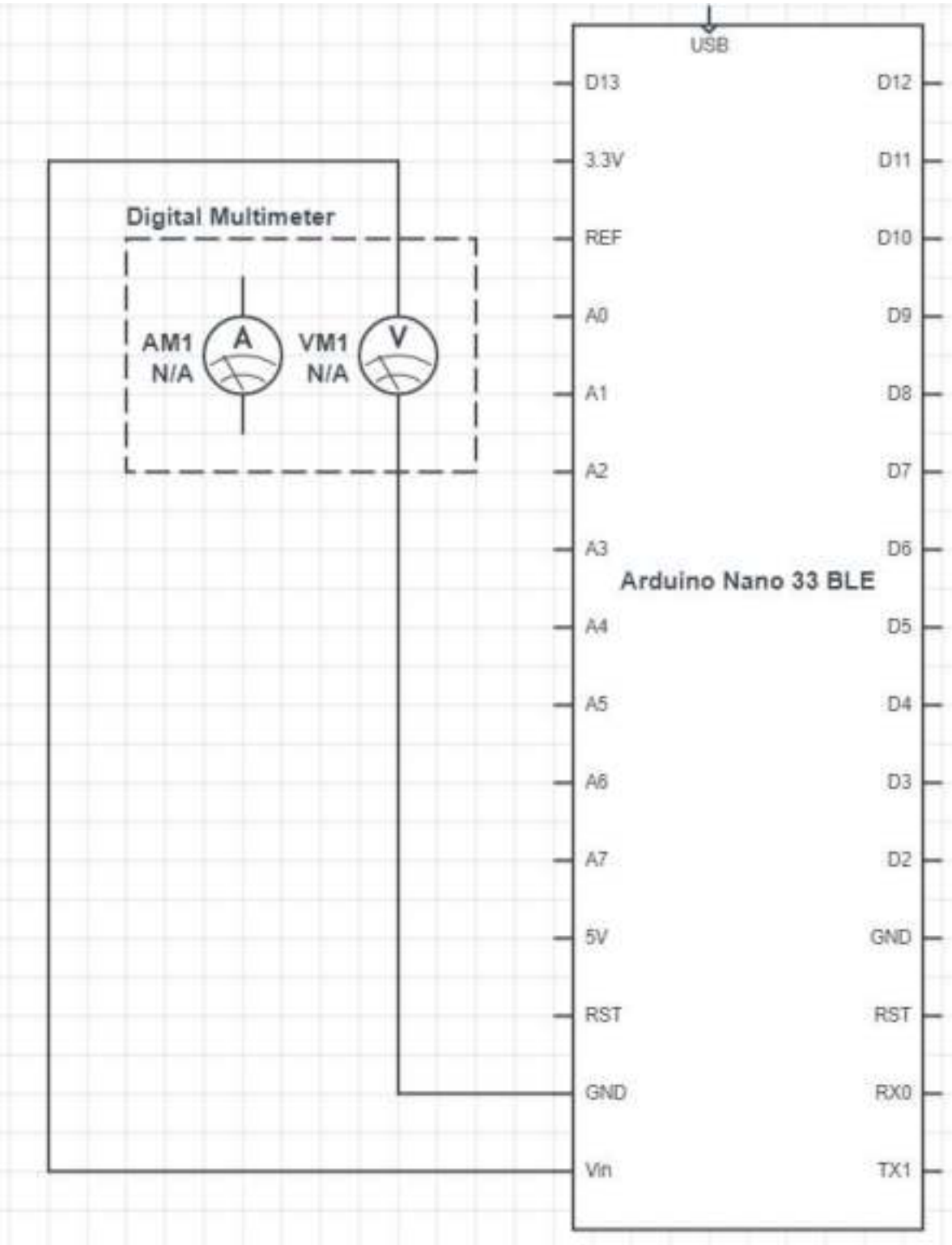


*Wilson, J. (2021, January 17). *Introduction to Arduino Nano 33 BLE*. The Engineering Projects. https://www.theengineeringprojects.com/2021/01/introduction-to-arduino-nano-33-ble.html.

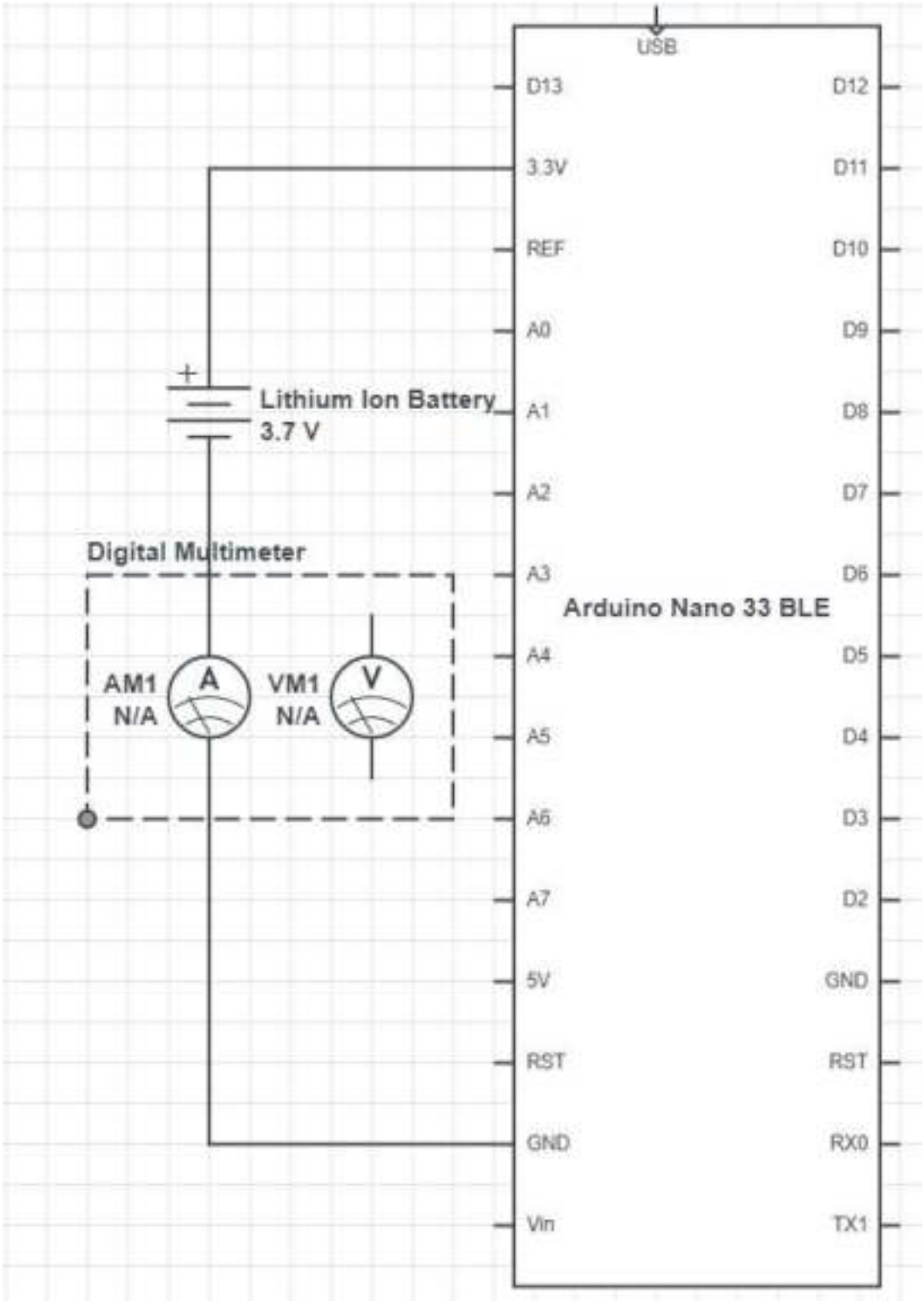
Schematic 2: Measuring 3.3V Voltage output pin



Schematic 2: Measuring 5V Voltage output pin



Schematic 3: Measuring Current Draw



APPENDIX 3: REFERENCE DATA TABLES

Table 1: Operating mode current consumption

Sample Rate	Power mode	Current consumption (mA)
14.9	Low-power	1.9
29.8	Low-power	2.4
113	Low-power	3.1
238	Normal-mode	4.3
476	Normal-mode	4.3
952	Normal-mode	4.3

Table 2: Electrical characteristics

Symbol	Parameter	Min	Tpy	Max	Uint
Vdd	Supply voltage	1.9		3.6	V
Vdd_IO	Module power supply for I/O	1.71		Vdd+0.1	
Idd_XM	Current consumption of the accelerometer and magnetic sensor in normal mode		600		μA
Idd_G	accelerometer and magnetic sensor in normal mode		4.0		mA

APPENDIX 4: DATA SHEETS

Table 1: Current and Voltage Measured

Measured Variable	Laptop Supply (5V)	Battery Supply (3.3V)
Voltage from pin V3.3 (V)		

Voltage from pin Vin (V)		
Current Draw I (mA)		

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 3. ***

Table 2: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 3: Observations of Data Collection

Observation	Comments

L. Current Withdraw Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Current Withdraw Verification has been completed for the Arduino Nano 33 BLE Microcontrtoller and Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The verification/validation acceptance criteria defined in the Current Withdraw were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must operate with a low current withdrawal. This is due to safety concerns so no electrical hazards are presented to the operator. This protocol will be used to verify the specified current withdrawal requirements for various users, which can be found in Appendix 1: *Current Withdraw Requirements and Specifications*.> and adheres to the approved specifications, concluding that the <Current Withdraw> capabilities have been verified.

2 Introduction/Background

Current Withdraw verification/validation has been completed for the Arduino Nano 33 BLE Microcontrtoller and Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The requirement for this verification/validation activity is due to new device lifecycle management (design control).

The <microcontroller and battery> are used to <control and power the brace>.

3 Objectives

The report summarizes the retrospective Current Withdraw Verification/validation has been completed for the Arduino Nano 33 BLE Microcontrtoller and Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification report is to document the objective evidence that:

- Preliminary equipment testing

4 References

The following references were used for this report:

1. Fast, Flexible Closed-Loop Feedback: Tracking Movement in "Real-Millisecond-Time", Keisuke Sehara, Viktor Bahr, Ben Mitchinson, Martin J. Pearson, Matthew E. Larkum, Robert N. S. Sachdev, eNeuro 14 October 2019, 6 (6) ENEURO.0147-19.2019
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augmented, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.).

https://store.arduino.cc/usa/nano-33-ble.

5 Materials/Equipment

The equipment used to execute this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Arduino IDE software v1.8.13
- Digital Multimeter

The materials used to execute this protocol are provided below:

- No test materials are required for this protocol

6 Methods

6.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

6.2 To measure the voltage output at the 3.3V and Vin pins of the Arduino Nano 33 BLE microcontroller connect the microcontroller to a laptop using a micro USB cable.

6.3 Connect the positive voltage port of a digital multimeter to 3.3V voltage pin and the COM port of the multimeter to the ground pin of the microcontroller. The circuit schematic for these connections can be found in Appendix 2. This measures the voltage output at the 3.3V voltage pin.

6.4 Connect the positive voltage port of a digital multimeter to Vin voltage pin and the COM port of the multimeter to the ground pin of the microcontroller. The circuit schematic for these connections can be found in Appendix 2. This measures the voltage output at the Vin voltage pin.

6.4 Disconnect the multimeter and micro USB. Connect the positive terminal of the battery to the 3.3V voltage pin on the microcontroller. Then connect the ground of the microcontroller to the Amp meter port of the multimeter. Then connect the COM port of the multimeter to the negative terminal on the battery to complete the circuit. The circuit schematic for these connections can be found in Appendix 2. This measures the current drawn in front of the microcontroller.

6.5 Compile the results from each measurement in Appendix 4, Table 1: Current and Voltage Measured.

Document all recorded data in Appendix 4: *Data Sheets*.

7 Results and Analysis

No calculations or statistical analysis is required since measurements are observed.

8 Conclusions & Assessment of Acceptance Criteria

The Current Withdraw Verification has been established by objective evidence that all key aspects of the Arduino Nano 33 BLE Microcontrtoller and Lithium Ion Battery Pack adheres to the approved specifications.

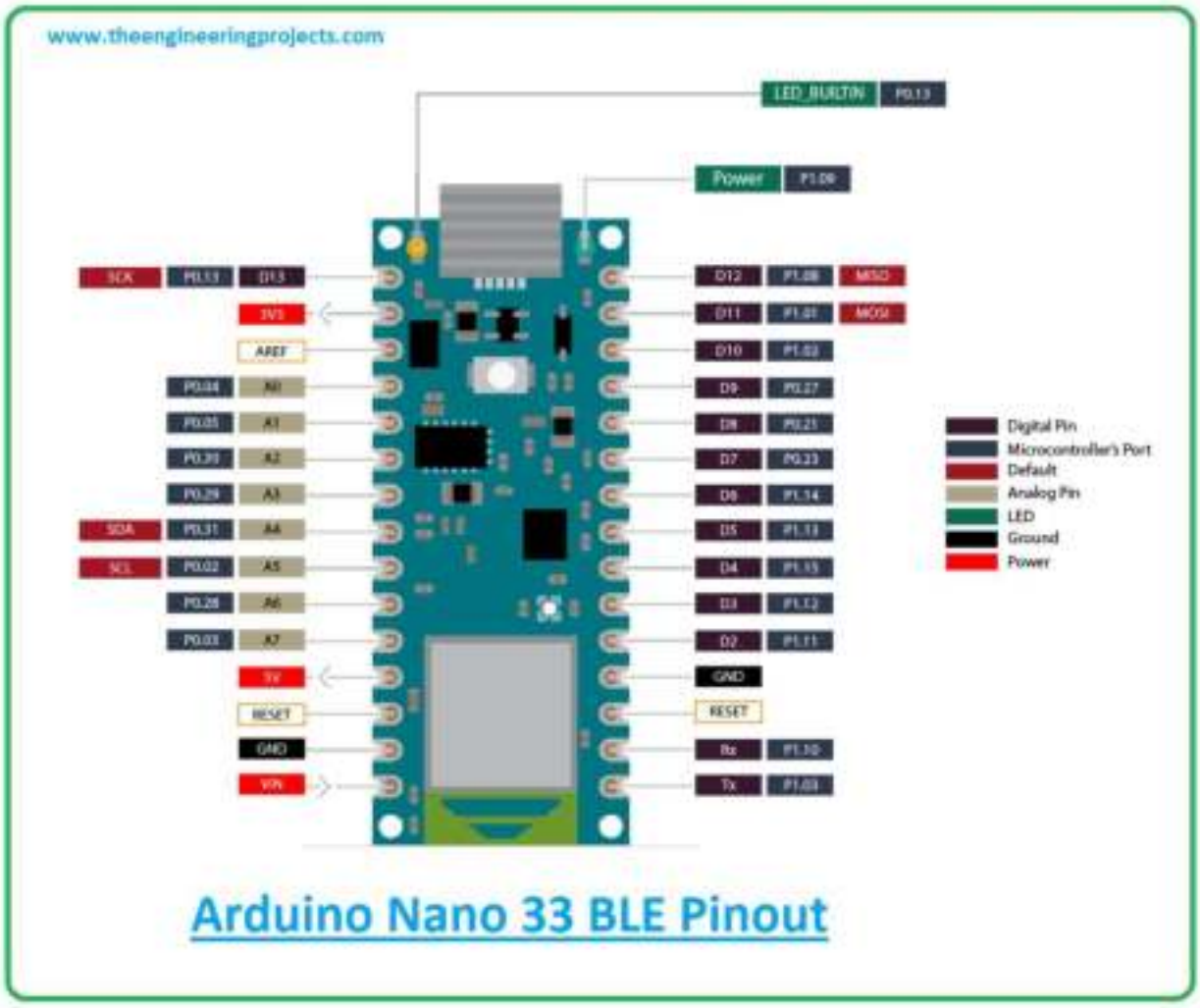
The Current Withdraw Verification has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 2).

9 Appendices

Appendix Number	Title
1	Circuit Schematics
2	Reference Sheets
3	Raw Data Sheets
	Design Inputs

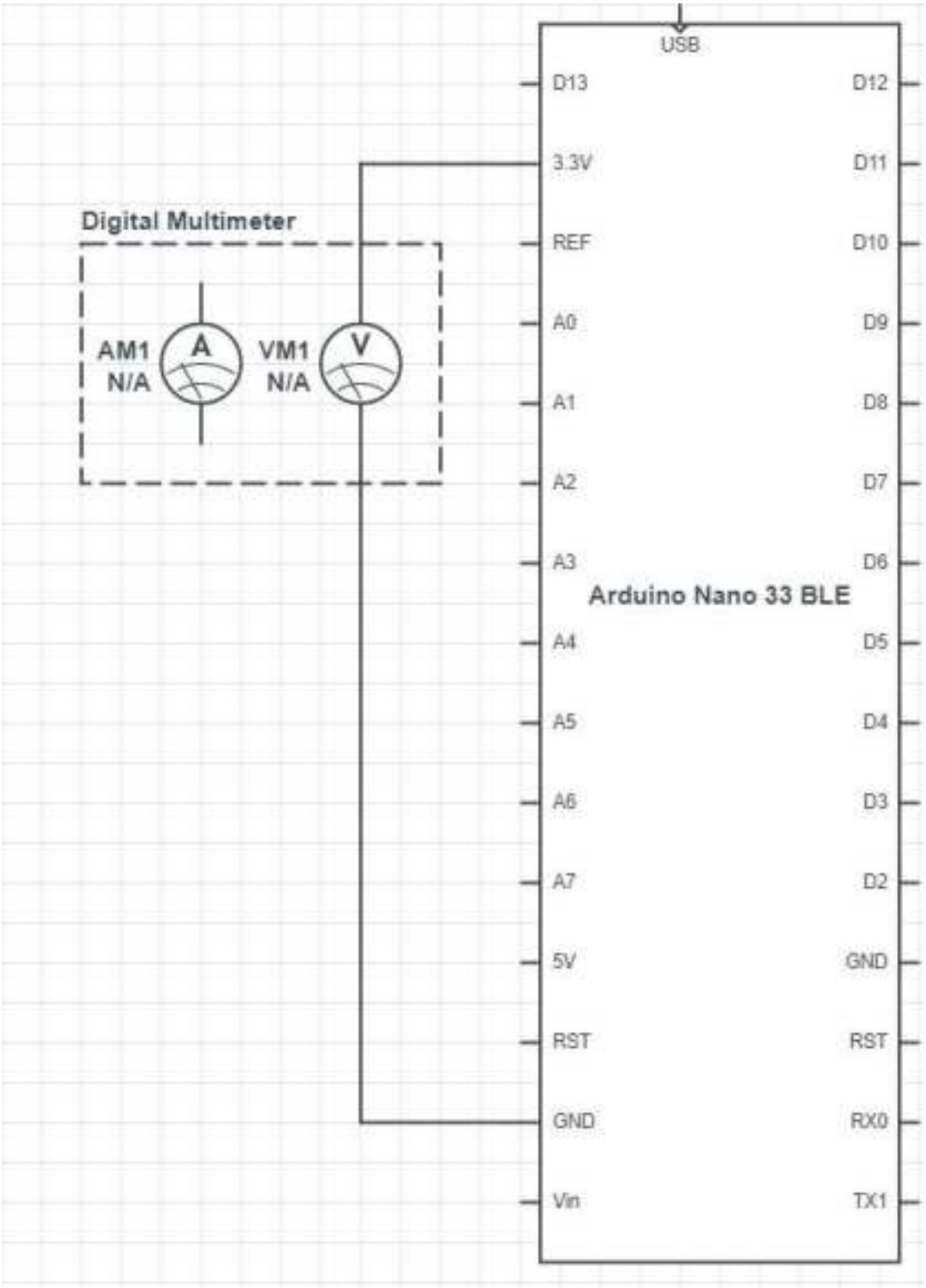
APPENDIX 1: CIRCUIT SCHEMATICS

Schematic 1: Arduino Nano 33 BLE Microcontroller Pinout

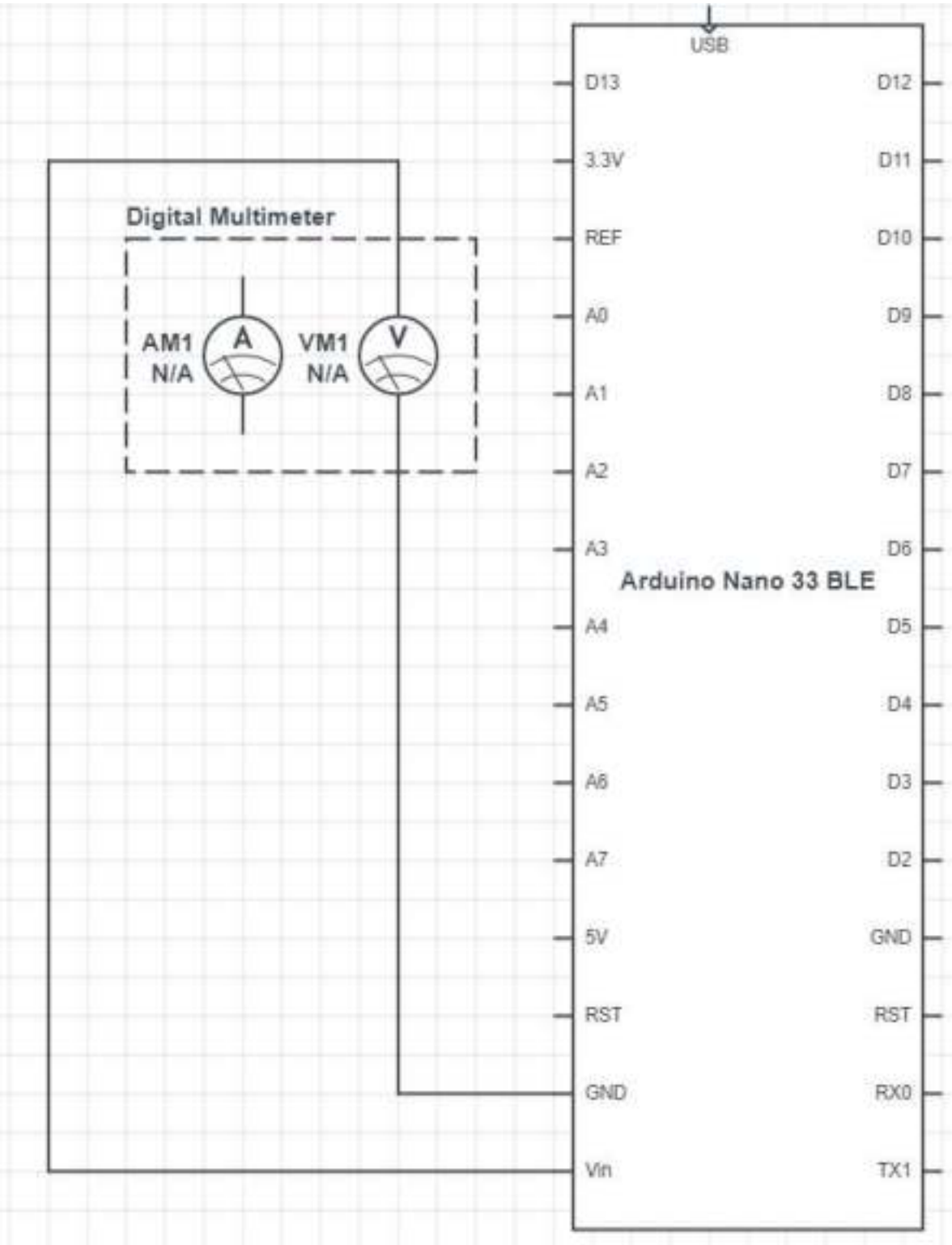


*Wilson, J. (2021, January 17). *Introduction to Arduino Nano 33 BLE*. The Engineering Projects. https://www.theengineeringprojects.com/2021/01/introduction-to-arduino-nano-33-ble.html.

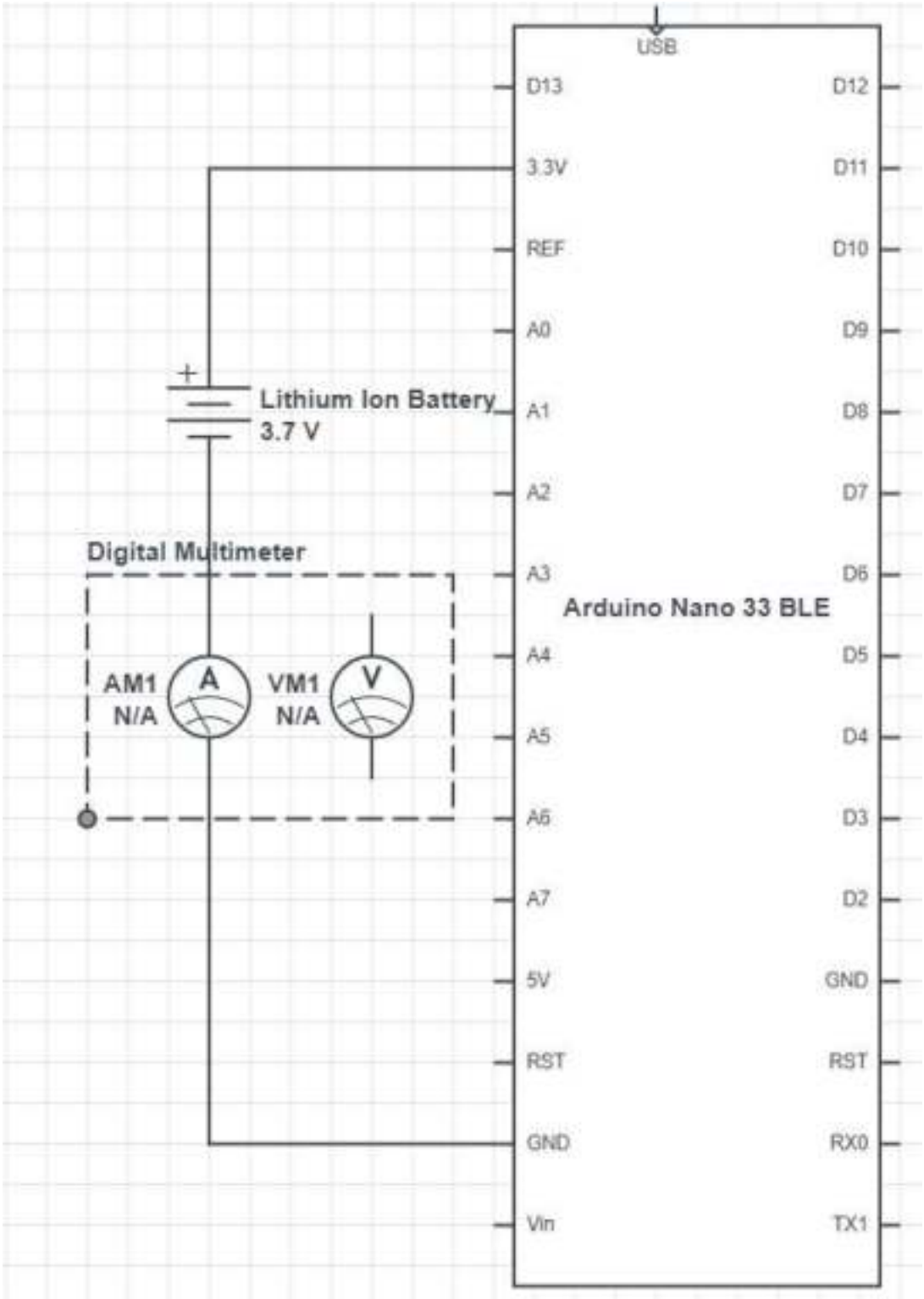
Schematic 2: Measuring 3.3V Voltage output pin



Schematic 2: Measuring 5V Voltage output pin



Schematic 3: Measuring Current Draw


USB
D13
D12
3.3V
D11
REF
D10
A0
D9
+
Lithium Ion Battery
3.7 V
A1
D8
A2
D7
Digital Multimeter
A3
D6
Arduino Nano 33 BLE
AM1
N/A
A
VM1
N/A
V
A4
D5
A5
D4
A6
D3
A7
D2
5V
GND
RST
RST
GND
RX0
Vin
TX1

APPENDIX 2: REFERENCE SHEETS

Table 1: Operating mode current consumption

Sample Rate	Power mode	Current consumption (mA)
14.9	Low-power	1.9
29.8	Low-power	2.4
113	Low-power	3.1
238	Normal-mode	4.3
476	Normal-mode	4.3
952	Normal-mode	4.3

Table 2: Electrical characteristics

Symbol	Parameter	Min	Tpy	Max	Uint
Vdd	Supply voltage	1.9		3.6	V
Vdd_IO	Module power supply for I/O	1.71		Vdd+0.1	
Idd_XM	Current consumption of the accelerometer and magnetic sensor in normal mode		600		μA
Idd_G	accelerometer and magnetic sensor in normal mode		4.0		mA

APPENDIX 3: RAW DATA SHEETS

Table 1: Voltage and Current Measurements

Measured Variable	Laptop Supply (5V)	Battery Supply (3.3V)
Voltage from pin V3.3 (V)	3.290 V	3.226 V
Voltage from pin Vin (V)	4.861 V	3.816 V
Current Draw I (mA)		11.8 mA

APPENDIX 2: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

M. Data Recording Verification Protocol [JW & AlC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the device must record positional data and force data during exercise/movement. The brace is composed of various electronic components, such as an accelerometer, gyroscope, and sensors to record the angles of the knee and the position of the knee throughout the user's gait cycle. It is important that the data recording features are capable of recording this positional data during movement and exercise. This protocol will be used to verify the specified data recording requirements, which can be found in Appendix 1: *Data Recording Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the data recording components of the knee brace can record positional data during movement/exercise (Appendix 1). This study will include the following:

1. Preliminary equipment testing
2. Circuit connection for IC2 communication
3. Test code for data sampling while moving

3 References

The references used for this protocol are provided in below:

1. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augment, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.). https://store.arduino.cc/usa/nano-33-ble.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Arduino IDE software v1.8.13

No test materials are required for this protocol.

5 Methods

5.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

5.2 Attach the microcontroller to the laptop using a micro USB cable for uploading code and serial communication.

5.3 Connect the LSM9DS1 inertial mass unit sensor to the Arduino Nano 33 BLE microcontroller via IC2 communication. To do this connect the ground pin on the LSM9DS1 breakout board to the ground pin on the microcontroller. Connect the 3.3V voltage pin on the breakout board to the Vin pin on the microcontroller. Connect the SCL pin on the breakout board to pin A5 SCL on the microcontroller and the SDA pin to A4 SDA for IC2 communication. The circuit schematic for these connections can be found in Appendix 2.

5.4 Download and launch the Arduino IDC software v1.8.13 on the laptop. Compile and upload the test code for testing the on board and LSM9DS1 inertial sensors. This will read data for each of the sensors (accelerometer, gyroscope, and magnetometer) in the x, y, and z directions.

5.5 Run the code while moving the sensor around to test for maximum and minimum values for the sensors. Open the serial monitor in the Arduino IDE software to see the data being collected and copy and paste the data into excel for analysis. Compile the results in Appendix 4 Table 1: Sensor Range Test for Accelerometer, Gyroscope and Magnetometer.

5.6 Run the code while wearing the brace and walking to collect data on the walking gait cycle. Open the serial monitor in the Arduino IDE software to see the data being collected and copy and paste the data into excel for analysis. Compile the results in Appendix 3 Table 3: Sensor Range Test for Sensors While Walking.

Document all recorded data in Appendix 3: *Data Sheets*.

6 Calculations Statistical Methods

The data is copied into excel where the maximum and minimum values are found using the excel functions:

MAX(number1, [number2], ...)
MIN(number1, [number2], ...)

The average minimum and maximum ranges for the sensors can be found using the following equation:

Average Angle = (Sum of Trials 1-3 Range) / 3

No statistical analysis is required since the range measurements are independent of the user and environmental effects.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Motion	Specification
Flexion / Extension / Rotation	Must be able to record data
Angles / Speed / Steps per minute	Must be able to record data

8 Appendices

Appendix Number	Description
1	Data Recording Requirements and Specifications
2	Circuit Schematics
3	Data Sheets
4	Code

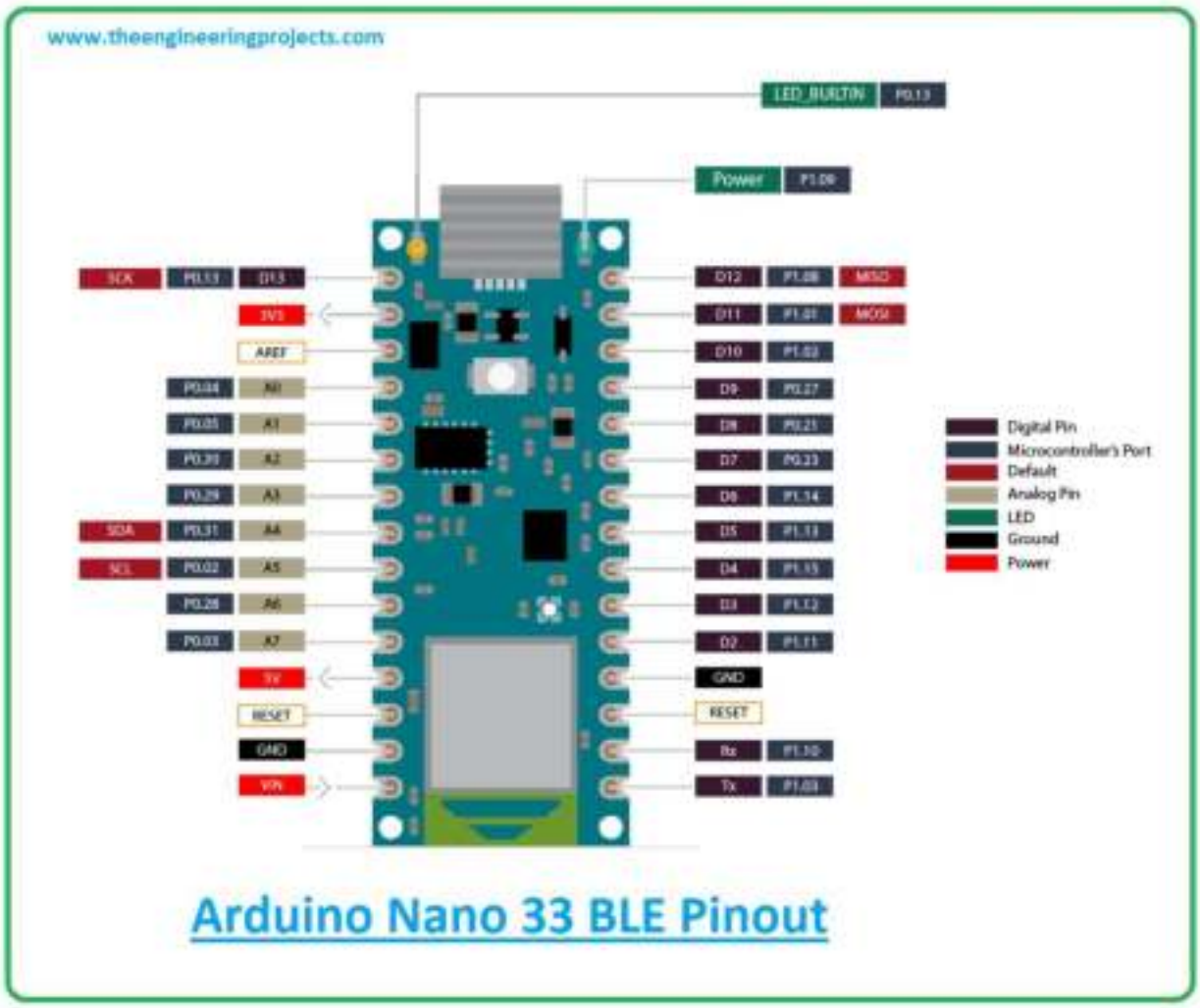
APPENDIX 1: DATA RECORDING REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion / Extension / Rotation ● Angles / Speed / Steps per minute	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation

Justification: Data collection during sessions with the patient is necessary for analyzing forces, knee angles, and other aspects of gait rehabilitation.

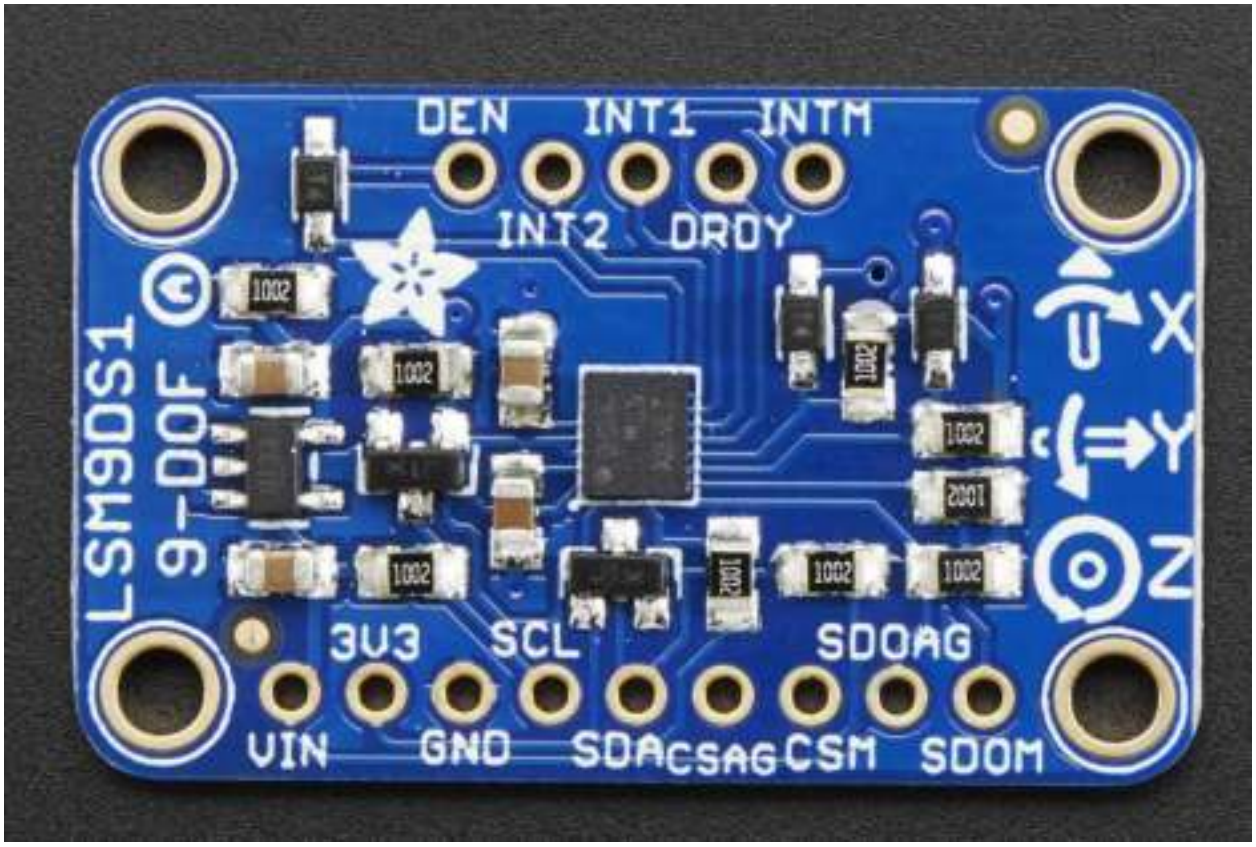
APPENDIX 2: CIRCUIT SCHEMATICS

Schematic 1: Arduino Nano 33 BLE Microcontroller Pinout



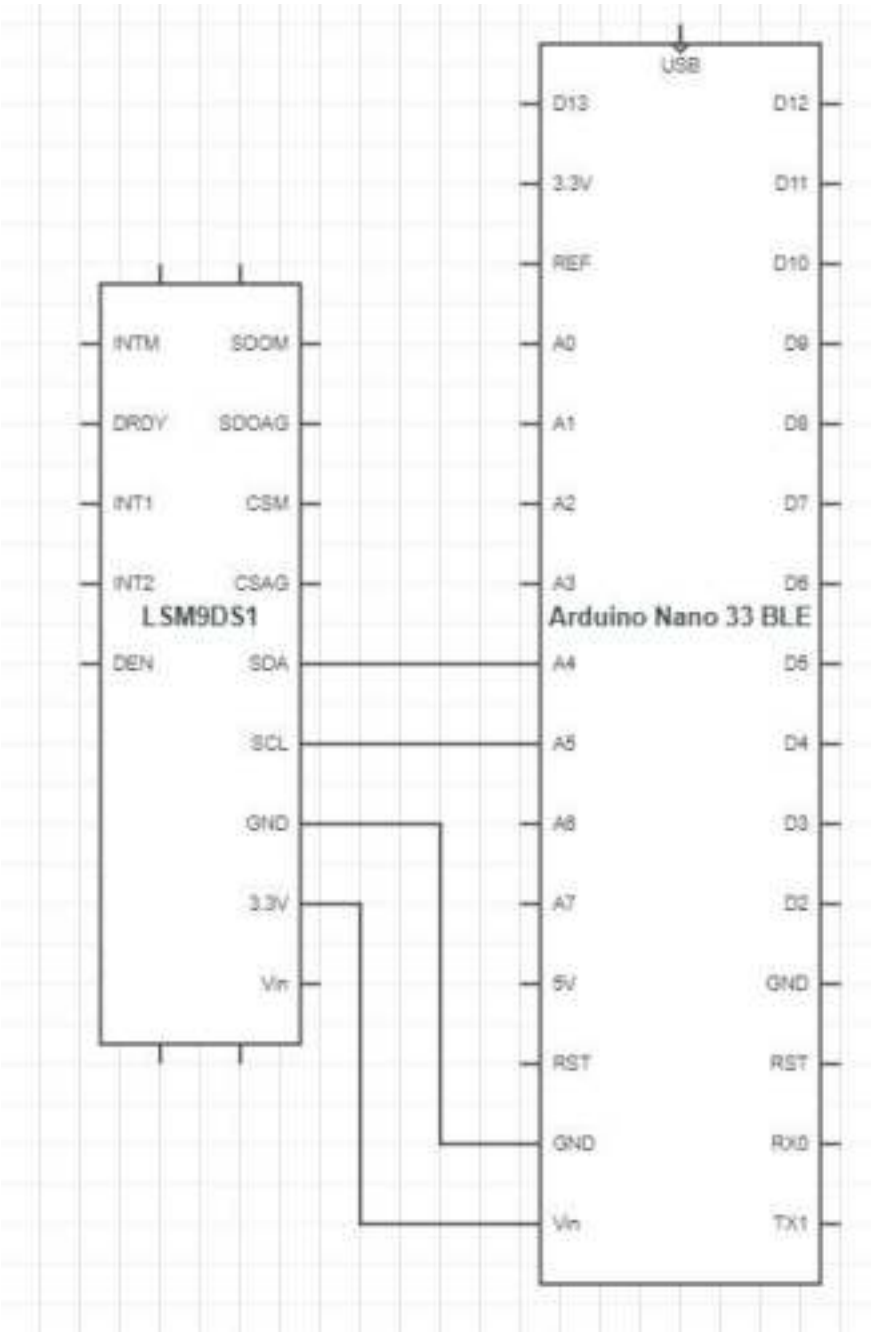
*Wilson, J. (2021, January 17). *Introduction to Arduino Nano 33 BLE*. The Engineering Projects. https://www.theengineeringprojects.com/2021/01/introduction-to-arduino-nano-33-ble.html.

Schematic 2: LSM9DS1 IMU Pinout



*Ada, L. (n.d.). *Adafruit LSM9DS1 Accelerometer + Gyro + Magnetometer 9-DOF Breakout*. Adafruit Learning System. https://learn.adafruit.com/adafruit-lsm9ds1-accelerometer-plus-gyro-plus-magnetometer-9-dof-breakout/pinouts.

Schematic 2: IC2 Communication



APPENDIX 3: REFERENCE DATA TABLES

Table 1: Data Sheet Sensor Range

Sensor	**FS Range**			
Accelerometer (g)	±2	±4	±8	±16
Magnetometer (dps)	±4	±8	±12	±16
Gyroscope (gauss)	±245	±500	±2000	

APPENDIX 4: DATA SHEETS

Table 1: Sensor Range Test for Accelerometer, Gyroscope and Magnetometer

Sensor (unit) range dir	**Trial 1**	**Trial 2**	**Trial 3**	**Avg**
Accelerometer (g) ±16 x				
Accelerometer (g) ±16 y				
Accelerometer (g) ±16 z				
Magnetometer (dps) ±16 x				
Magnetometer (dps) ±16 y				
Magnetometer (dps) ±16 z				
Gyroscope (gauss) ±2000 x				
Gyroscope (gauss) ±2000 y				
Gyroscope (gauss) ±2000 z				

Table 2: Sensor Range Test for Sensors While Walking.

Sensor (unit) range dir	**Trial 1**	**Trial 2**	**Trial 3**	**Avg**
Accelerometer (g) ±16 x				
Accelerometer (g) ±16 y				
Accelerometer (g) ±16 z				
Magnetometer (dps) ±16 x				
Magnetometer (dps) ±16 y				
Magnetometer (dps) ±16 z				
Gyroscope (gauss) ±2000 x				
Gyroscope (gauss) ±2000 y				
Gyroscope (gauss) ±2000 z				

*** Note any changes or deviations as applicable. If a mistake is made, put a single line through the data, put a circled number next to the crossed out data point (i.e. ---- ①), and in the Deviation Table 3 below, write the number, your initials, the date modified, and the corrected value / justification for crossing out the recorded data. Note any observations in Table 4. ***

Table 3: Deviations to Data Sheets

Number	Initials	Date	Correct Value	Justification

Table 4: Observations of Data Collection

Specification	Trial #	Observation

APPENDIX 4: CODE

N. Data Recording Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Data Recording verification has been completed for the Arduino Nano 33 BLE and LMS9DS1 inertial mass unit sensor located in room BME 218 at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the data recording verification were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that Arduino Nano 33 BLE and LMS9DS1 inertial mass unit sensor can read accurate data and adheres to the approved specifications, concluding that the data recording verification capabilities have been verified.

2 Introduction/Background

The data recording verification relates to the Arduino Nano 33 BLE and LMS9DS1 inertial mass unit sensor located in room BME 218 at The College of New Jersey, Ewing, NJ.

The requirement for this data recording verification activity is due to new device lifecycle management (design control).

The Arduino Nano 33 BLE and LMS9DS1 inertial mass unit sensor is used to control the device and record data on the users gait cycle.

3 Objectives

The report summarizes the retrospective data recording verification for the The Arduino Nano 33 BLE and LMS9DS1 inertial mass unit sensor located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this data recording verification report is to document the objective evidence that:

- To verify that the data recording components of the knee brace can record positional data during movement/exercise.
- To verify the sensors measuring range capabilities.

4 References

The following references were used for this report:

1. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020
2. LSM9DS1 iNEMO inertial module: 3D accelerometer, 3D gyroscope, 3D magnetometer Datasheet, ST life.augment, March 2015, https://www.st.com/resource/en/datasheet/lsm9ds1.pdf
3. *Arduino Nano 33 BLE*. Arduino Nano 33 BLE | Arduino Official Store. (n.d.). https://store.arduino.cc/usa/nano-33-ble.

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- No test materials are required for this protocol.

The equipment used to execute this protocol are provided below:

- Arduino Nano 33 BLE Microcontroller
- LSM9DS1 Inertial Sensor
- Laptop
- Micro USB
- Jumper connecting wires
- Arduino IDE software v1.8.13

6 Methods

6.1 For ease of prototype testing, solder the Arduino Nano 33 BLE microcontroller and LSM9DS1 breakout board pins to pin headers so they can be placed in a breadboard.

6.2 Attach the microcontroller to the laptop using a micro USB cable for uploading code and serial communication.

6.3 Connect the LSM9DS1 inertial mass unit sensor to the Arduino Nano 33 BLE microcontroller via IC2 communication. To do this connect the ground pin on the LSM9DS1 breakout board to the ground pin on the microcontroller. Connect the 3.3V voltage pin on the breakout board to the Vin pin on the microcontroller. Connect the SCL pin on the breakout board to pin A5 SCL on the microcontroller and the SDA pin to A4 SDA for IC2 communication. The circuit schematic for these connections can be found in Appendix 2.

6.4 Download and launch the Arduino IDC software v1.8.13 on the laptop. Compile and upload the test code for testing the on board and LSM9DS1 inertial sensors. This will read data for each of the sensors (accelerometer, gyroscope, and magnetometer) in the x, y, and z directions.

6.5 Run the code while moving the sensor around to test for maximum and minimum values for the sensors. Open the serial monitor in the Arduino IDE software to see the data being collected and copy and paste the data into excel for analysis. Compile the results in Appendix 3 Table 1: Sensor Range Test for Accelerometer, Gyroscope and Magnetometer.

6.6 Run the code while wearing the brace and walking to collect data on the walking gait cycle. Open the serial monitor in the Arduino IDE software to see the data being collected and copy and paste the data into excel for analysis. Compile the results in Appendix 3 Table 3: Sensor Range Test for Sensors While Walking.

7 Results and Analysis

The data is copied into excel where the maximum and minimum values are found using the excel functions:

MAX(number1, [number2], ...)
MIN(number1, [number2], ...)

The average minimum and maximum ranges for the sensors can be found using the following equation:

Average Angle = (Sum of Trials 1-3 Range) / 3

These ranges were compiled in Appendix 3 and evaluated against the reference sheets in Appendix 2 and all tests met the requirements of the protocol. Then the raw data was collected while moving the sensor around and during the walking gait cycle and verified for accuracy shown in Appendix 3.

8 Conclusions & Assessment of Acceptance Criteria

The Data Recording verification has been established by objective evidence that all key aspects of the Arduino Nano 33 BLE and LMS9DS1 adheres to the approved specifications.

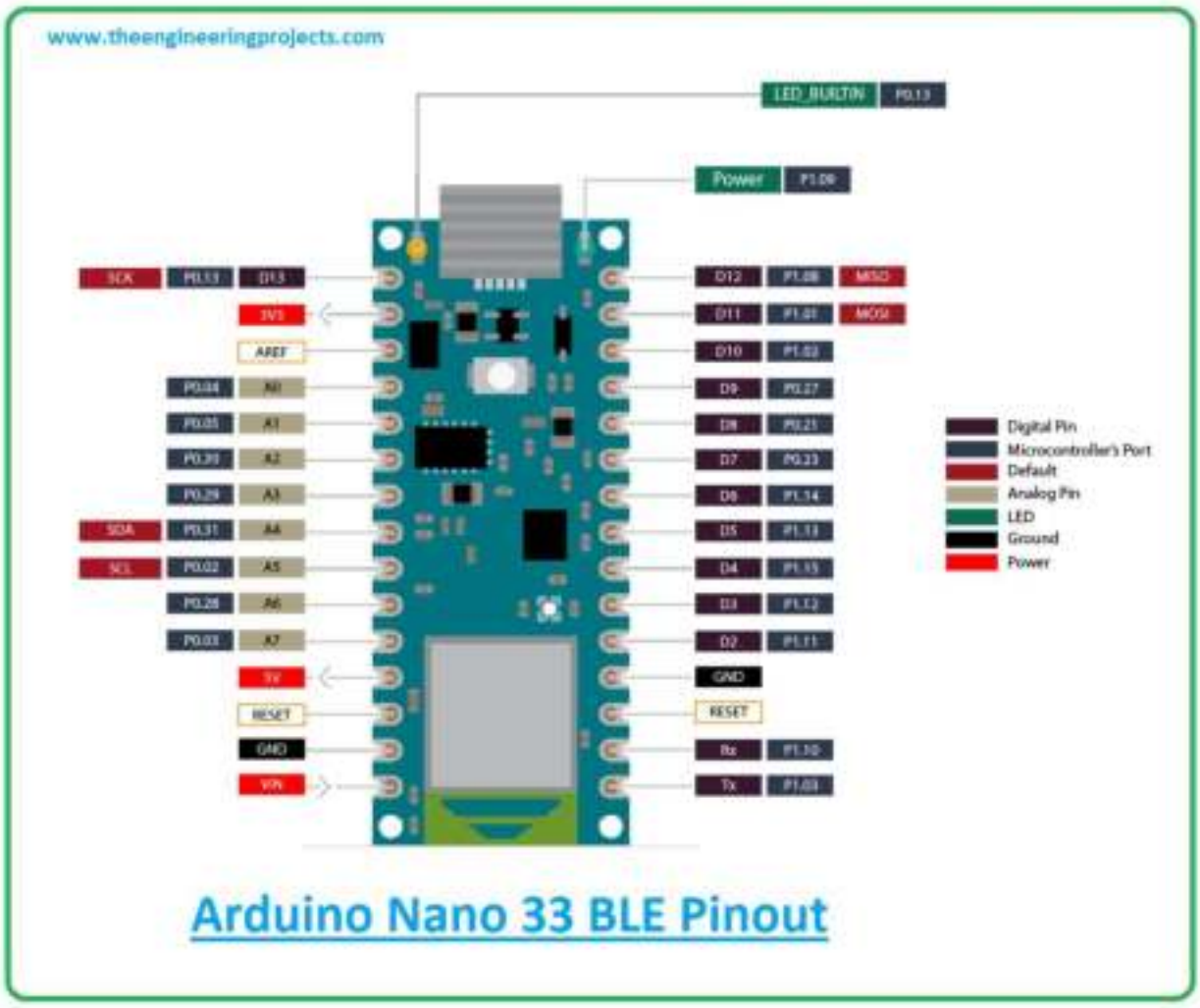
The Data Recording verification has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 4).

9 Appendices

Appendix Number	Title
1	Circuit Schematics
2	Reference Sheets
3	Raw Data Sheets
4	Design Inputs

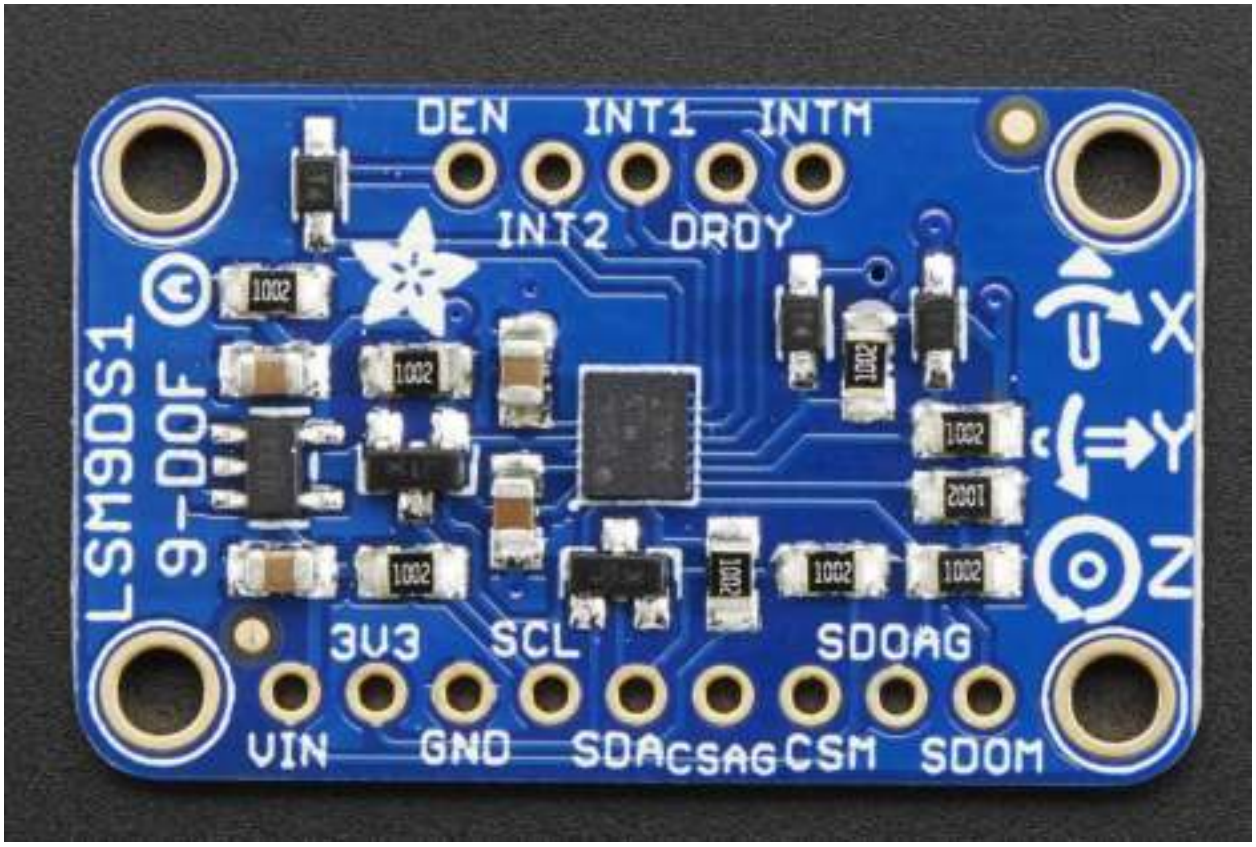
APPENDIX 1: CIRCUIT SCHEMATICS

Schematic 1: Arduino Nano 33 BLE Microcontroller Pinout



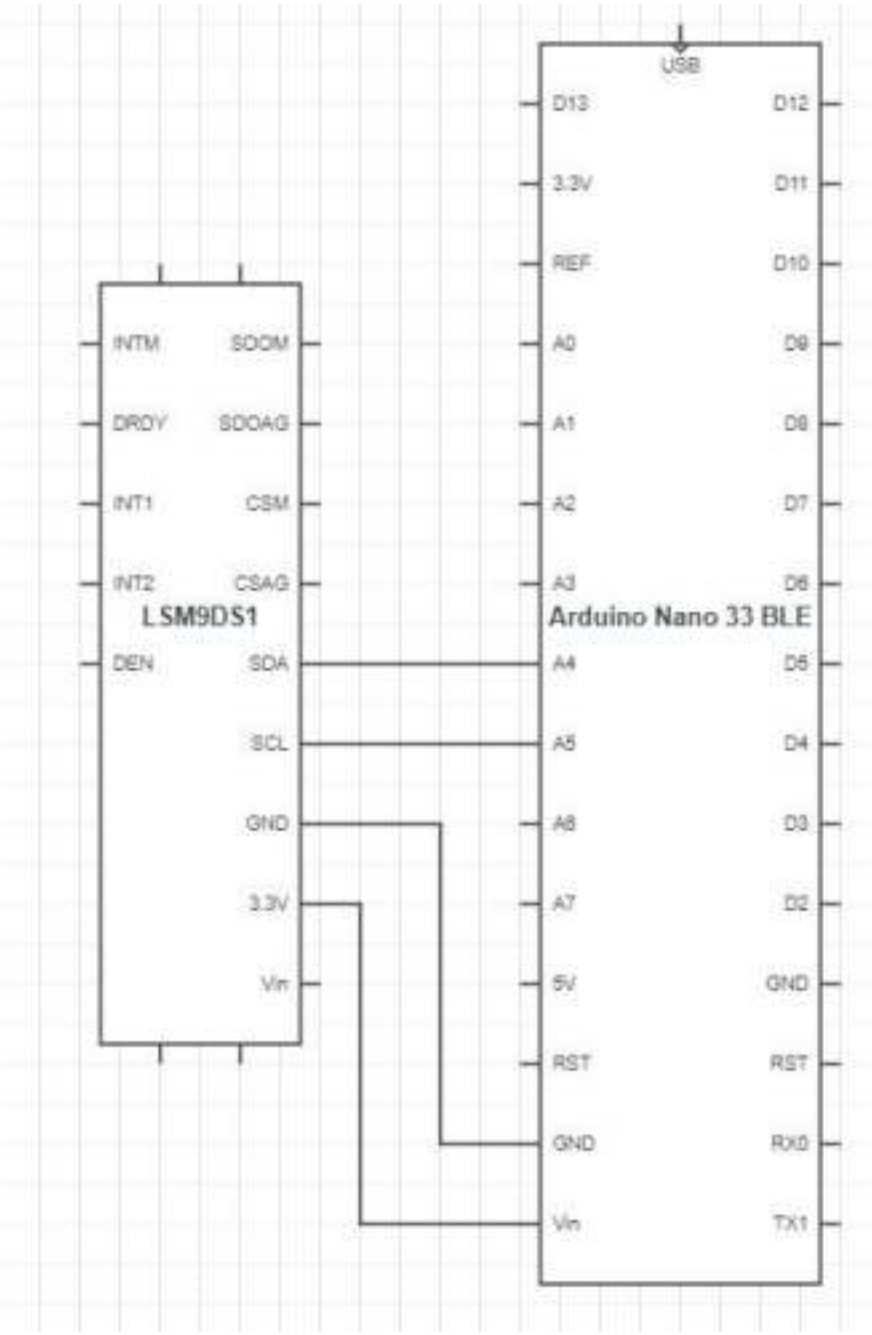
*Wilson, J. (2021, January 17). *Introduction to Arduino Nano 33 BLE*. The Engineering Projects. https://www.theengineeringprojects.com/2021/01/introduction-to-arduino-nano-33-ble.html.

Schematic 2: LSM9DS1 IMU Pinout



*Ada, L. (n.d.). *Adafruit LSM9DS1 Accelerometer + Gyro + Magnetometer 9-DOF Breakout*. Adafruit Learning System. https://learn.adafruit.com/adafruit-lsm9ds1-accelerometer-plus-gyro-plus-magnetometer-9-dof-breakout/pinouts.

Schematic 3: IC2 Communication



APPENDIX 2: REFERENCE SHEETS

Table 1: Data Sheet Sensor Range

Sensor	**FS Range**			
Accelerometer (g)	±2	±4	±8	±16
Magnetometer (dps)	±4	±8	±12	±16
Gyroscope (gauss)	±245	±500	±2000	

APPENDIX 3: RAW DATA SHEETS

Table 1: Sensor Range Test for Accelerometer, Gyroscope and Magnetometer

Sensor (unit) range (direction)	**Trial 1**	**Trial 2**	**Trial 3**	**Avg**
Accelerometer (g) ±16 x	± 24	± 24	± 24	± 24
Accelerometer (g) ±16 y	± 24	± 24	± 24	± 24
Accelerometer (g) ±16 z	± 24	± 24	± 24	± 24
Magnetometer (dps) ±16 x	±16	±16	±16	±16
Magnetometer (dps) ±16 y	±16	±16	±16	±16
Magnetometer (dps) ±16 z	±16	±16	±16	±16
Gyroscope (gauss) ±2000 x	±2000	±2000	±2000	±2000
Gyroscope (gauss) ±2000 y	±2000	±2000	±2000	±2000
Gyroscope (gauss) ±2000 z	±2000	±2000	±2000	±2000

Figure 1: Inertial Mass Unit data for Data Recording for Movement

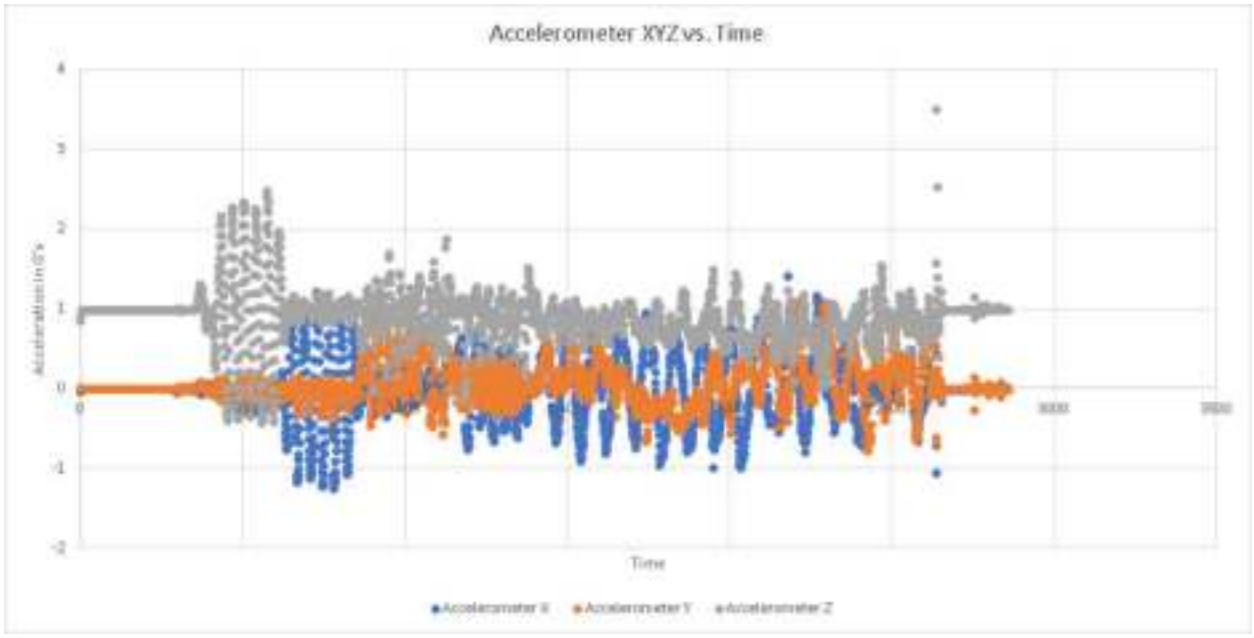


Figure 2: Inertial Mass Unit data for Data Recording During Walking Gait

APPENDIX 4: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

O. External Moisture Shielding Verification Protocol [JW & AvC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must fit the average male/female elderly patient's legs. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users. This protocol will be used to verify the specified size requirements for various users, which can be found in Appendix 1: *External Moisture Shielding Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace design will not cause any electrical hazards to the user (Appendix 1). This study will include the following:

1. Perspiration of water onto the fully assembled adaptable knee brace while operating the device

3 References

The references used for this protocol are provided in below:

1. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Fully assembled adaptable knee brace
- Spray bottle to perspire water onto the device

The test materials required for this protocol are provided below:

- water

5 Methods

5.1 All electronics will be placed in a plastic housing and all exposed wires will be covered with heat shrink tubing.

5.2 Electronic casings and exposed metal will be tested for shielding by exposing it to perspiration like moisture mimicking posible perspiration that can occur during use.

5.3 All electronic and exposed metal will then be examined for any damaging effects produced from the moisture.

Document all recorded data in Appendix 2: *Data Sheets*.

6 Calculations Statistical Methods

Surface Area exposed to moisture will be measured and compared via parts showing corrosion to parts unaffected by moisture. The percentage will be calculated through a ratio of these variables:

$$Surface\ Area\ Affected\ by\ Moisture\ =\ \ ff\ /\ Total\ Surface\ Area$$

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Components	Specification
Electronic Components	No damage / alterations in function after perspiration with water

8 Appendix

Appendix Number	Description
1	External Moisture Sheiling Requirements and Specifications
2	Data Sheets

APPENDIX 1: EXTERNAL MOISTURE SHIELDING REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [1]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage

Justification: During sessions and exposure to elements, the hazards can be mitigated by shielding the electrical components. The battery for the device should last one charge per session to reduce injury risk and ensure data collection throughout the entire session.

APPENDIX 2: DATA SHEETS

Table 1: Observations of Data Collection

Specification	Observation

P. External Moisture Shielding Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

External Moisture Verification has been completed for the physical brace with electrical components encased located in room BME 218 at The College of New Jersey, Ewing, NJ.

The External Moisture Verification acceptance criteria defined in the <protocol name> were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that <insert explanation of the device component meeting the purpose of the verification/validation protocol> and adheres to the approved specifications, concluding that the External Moisture Verification capabilities have been verified.

2 Introduction/Background

The External Moisture Verification relates to the physical brace with electrical components encased located in room BME 218 at The College of New Jersey, Ewing, NJ.

The requirement for this verification/validation activity is due to new device lifecycle management (design control).

The physical brace with electrical components encased is used to protect the electrical components from hazards.

3 Objectives

The report summarizes the retrospective External Moisture Verification for the <insert device component> located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification/validation report is to document the objective evidence that:

- The objective of this protocol is to verify that the knee brace design will not cause any electrical hazards to the user

4 References

The following references were used for this report:

1. Alonge, F., Cucco, E., D'Ippolito, F., & Pulizzotto, A. (2014, May 13). The Use of Accelerometers and Gyroscopes to Estimate Hip and Knee Angles on Gait Analysis. Retrieved September 16, 2020

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- Water

The equipment used to execute this protocol are provided below:

- Fully assembled adaptable knee brace
- Spray bottle to perspire water onto the device

6 Methods

6.1 All electronics will be placed in a plastic housing and all exposed wires will be covered with heat shrink tubing.

6.2 Electronic casings and exposed metal will be tested for shielding by exposing it to perspiration like moisture mimicking posible perspiration that can occur during use.

6.3 All electronic and exposed metal will then be examined for any damaging effects produced from the moisture.

7 Results and Analysis

Surface Area exposed to moisture will be measured and compared via parts showing corrosion to parts unaffected by moisture. The percentage will be calculated through a ratio of these variables:

$$Surface\ Area\ Affected\ by\ Moisture\ =\ \ ff\ /\ Total\ Surface\ Area$$

All tests met the requirements of the protocol.

8 Conclusions & Assessment of Acceptance Criteria

The <verification/validation protocol name> has been established by objective evidence that all key aspects of the <insert device component> adheres to the approved specifications.

The <verification/validation activity name> has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 2).

9 Appendices

Appendix Number	Title
1	Raw Data Sheets
2	Design Inputs

APPENDIX 1: RAW DATA SHEETS

APPENDIX 2: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

Q. Battery Verification Protocol [JW & AlC]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the brace battery must last throughout the duration of the gait therapy session with a physical therapy (PT) specialist. Typical PT sessions last 1 hour, so the battery must be able to be fully operational for 1 hour without the battery dying. This protocol will be used to verify the specified battery requirements, which can be found in Appendix 1: *Battery Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the battery for the brace will last throughout a 1 hour PT session (Appendix 1). This study will include the following:

1. Full operation of the brace on a user for 1 hour while the battery life is monitored incrementally.

3 References

The references used for this protocol are provided in below:

1. Paluska, S. A., & McKeag, D. B. (2000). Knee braces: current evidence and clinical recommendations for their use. American family physician, 61(2), 411–424.

4 Materials/Equipment

The test equipment required for this protocol are provided below:

- Battery
- Timer
- Fully Assembled Adaptable Knee Brace
- Computer that can hook up to electronics

There are no test materials required for this protocol.

5 Methods

5.1 Attach the brace to an operator so that the brace is secure against the operator's leg and the straps are tightened to comfort. Ensure the battery has been fully charged; if not, charge the battery prior to executing this protocol.

5.2 Set a timer to 1 hour. When the operator is ready, start the timer.

5.3 During the 1 hour test period, have the operator walk around and perform various movements, included but not limited to: walking, running, jumping, squatting, standing, sitting (for no more than a couple minute increments at a time), etc. Be sure to record the timeframe when each action was being performed as reference for all data being recorded.

5.4 At the completion of the 1 hour timeframe, check the battery's capacity using a multimeter, or other device. Record the device used in the completion report.

5.5 Repeat this test 2 times.

Note: If the battery fails any of the trials, it fails this protocol.

Attach any recorded data in the completion report.

6 Calculations Statistical Methods

Since this is a visual inspection, statistical analysis is not required. No calculations are required for this protocol.

7 Acceptance Criteria

The criteria for success must meet the following:

Table 1: Criteria for Success

Test	Specification
1 hour session	Battery must be capable of supporting full operation of the knee brace for ≥ 1 hour

8 Appendix

Appendix Number	Description
1	Battery Requirements and Specifications

APPENDIX 1: BATTERY REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour

Justification: During sessions and exposure to elements, the hazards can be mitigated by shielding the electrical components. The battery for the device should last one charge per session to reduce injury risk and ensure data collection throughout the entire session.

R. Battery Verification Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Battery Capacity Verification has been completed for the Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The Battery Capacity Verification acceptance criteria defined in the Battery Verification Protocol were satisfactorily met, as summarized in Appendix 2. The testing conducted establishes that Lithium Ion Battery Pack has sufficient capacity to power the brace for the period of gait analysis and adheres to the approved specifications, concluding that the Battery Capacity Verification capabilities have been verified.

2 Introduction/Background

The Battery Capacity Verification relates to the Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The requirement for this Battery Capacity Verification activity is due to new device lifecycle management (design control).

The Battery Capacity Verification is used to power the microcontroller, servo, and LSM9DS1 sensor on the brace.

3 Objectives

The report summarizes the retrospective Battery Capacity Verification for the Lithium Ion Battery Pack located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification/validation report is to document the objective evidence that:

- Full operation of the brace on a user for 1 hour while the battery life is monitored incrementally.

4 References

The following references were used for this report:

1. Paluska, S. A., & McKeag, D. B. (2000). Knee braces: current evidence and clinical recommendations for their use. American family physician, 61(2), 411–424.

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- There are no test materials required for this protocol.

The equipment used to execute this protocol are provided below:

- Battery
- Timer
- Fully Assembled Adaptable Knee Brace
- Computer that can hook up to electronics

6 Methods

6.1 Attach the brace to an operator so that the brace is secure against the operator's

leg and the straps are tightened to comfort. Ensure the battery has been fully charged; if not, charge the battery prior to executing this protocol.

6.2 Set a timer to 1 hour. When the operator is ready, start the timer.

6.3 During the 1 hour test period, have the operator walk around and perform various movements, included but not limited to: walking, running, jumping, squatting, standing, sitting (for no more than a couple minute increments at a time), etc. Be sure to record the timeframe when each action was being performed as reference for all data being recorded.

6.4 At the completion of the 1 hour timeframe, check the battery's capacity using a multimeter, or other device. Record the device used in the completion report.

6.5 Repeat this test 2 times.

Note: If the battery fails any of the trials, it fails this protocol.

7 Results and Analysis

$$Battery\ Life = \frac{Battery\ Capacity\ (mAh)}{Current\ draw\ from\ Battery\ (mA)}$$

$$Battery\ Life = \frac{6600\ (mAh)}{11.8\ (mA)} = 23.3\ days$$

The max current drawn from the batter during operation was 11.8mA which was slightly higher then the specification of 10mA, but was considered appropriate for the verification.

8 Conclusions & Assessment of Acceptance Criteria

The Battery Capacity Verification has been established by objective evidence that all key aspects of the Lithium Ion Battery Pack adheres to the approved specifications.

The Battery Capacity Verification has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 2).

9 Appendices

Appendix Number	Title
1	Reference Sheets
2	Raw Data Sheets
3	Design Inputs

APPENDIX 1: REFERENCE SHEETS

Table 1: Voltage and Current Specifications for LSM9DS1 Inertial Sensor

Symbol	**Parameter**	**min**	**Tpy**	**Max**	**Uint**
Vdd	Supply voltage	1.9		3.6	V
Vdd_IO	Module power supply for I/O	1.71		Vdd+0.1	
Idd_XM	Current consumption of the accelerometer and magnetic sensor in normal mode		600		μA
Idd_G	accelerometer and magnetic sensor in normal mode		4.0		mA

APPENDIX 2: RAW DATA SHEETS

Table 1: Battery Measured Voltage and Current

Computer Supply		**Battery Supply**	
Vin	4.861	Vin=V3.3	3.2262
V(3.3)	3.2902	V3.3=Vb	3.8159
		I (mA)	11.8

APPENDIX 3: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

S. Knee Brace Biocompatibility Verification Protocol [JW]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must be biocompatible in accordance with the required tests by the FDA per ISO 10993; The Adaptable Knee Brace is classified as a category B surface device. This protocol will be used to verify the biocompatibility of the knee brace by executing the required FDA tests for this brace, which can be found in Appendix 1: *Biocompatibility Requirements and Specifications*.

2 Objectives

The objective of this protocol is to verify that the knee brace design will be biocompatible with the user (Appendix 1). This study will include the following FDA biocompatibility tests for category B surface devices, as defined by ISO 10993:

1. Execution of the FDA Cytotoxicity Test
2. Execution of the FDA Sensitization & Irritation Test

3 References

The references used for this protocol are provided in below:

1. Paluska, S. A., & McKeag, D. B. (2000). Knee braces: current evidence and clinical recommendations for their use. American family physician, 61(2), 411–424.
2. Center for Devices and Radiological Health. “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry Food and Drug Administration Staff, September 2020. Doc # FDA-2013-D-0350.

4 Materials/Equipment

See Appendix 2, FDA Test Descriptions.

5 Methods

5.1 FDA Cytotoxicity Test

5.1.1 Reference Appendix 2, Cytotoxicity.

5.2 **FDA Sensitization & Irritation Test**

5.2.1 Reference Appendix 2, Sensitization

6 Calculations Statistical Methods

N/A

7 Acceptance Criteria

The criteria for success must meet the following:

Table 5: Criteria for Success

Test	Specification
Cytotoxicity (FDA Test)	Pass
Sensitization and Irritation (FDA Test)	Pass

8 Appendix

Appendix Number	Description
1	Biocompatibility Requirements and Specifications
2	FDA Test Descriptions

APPENDIX 1: BIOCOMPATIBILITY REQUIREMENTS AND SPECIFICATIONS

Requirement	Specification	Verification
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards

Justification: It is necessary for the device to be comfortable and biocompatible so that the user is not uncomfortable or gets further injury using the device.

APPENDIX 2: FDA TEST DESCRIPTIONS

A. CYTOTOXICITY

As per the FDA website:

If not otherwise addressed during the risk assessment process, for tests where the test article is extracted in growth media, we recommend that extractions be conducted at 37 °C for 24 to 72 hours using a vehicle that will allow for extraction of both polar and nonpolar constituents from the test article, such as mammalian cell culture media (e.g., MEM) supplemented with 5-10% serum.

For novel materials (i.e., materials that have not previously been used in a legally US marketed medical device with the same type and duration of contact), we recommend that both direct contact and elution methods be considered. For some devices, a direct contact study per ISO 10993-5 may be needed to better reflect clinical use. Depending on the nature and function of the material (e.g., coatings or surface topography modifications), a non-standard direct contact study, where the cells are grown on a material surface, may be needed if no implantation data are available.

For materials that are inherently cytotoxic, additional testing using various dilutions of the test solution may be necessary to determine the level at which cytotoxicity no longer occurs. This information can be evaluated with respect to the clinical dose as well as other mitigating factors such as duration of contact and clinical need (e.g., clinical benefits versus risks). For some devices, such as dental acid etchants, devices containing a known cytostatic/cytotoxic agent, or uncured polymer resins, additional comparative cytotoxicity testing using a legally US-marketed medical device may be necessary to demonstrate that the new device is no more cytotoxic than the comparative device with the same type and duration of contact.

B. SENSITIZATION

As per the FDA website:

There are two types of sensitization tests that are generally submitted in support of IDE and marketing applications: the Guinea Pig Maximization Test and the Local Lymph Node Assay. In addition, the Buehler method can be used for topical devices only (i.e., those in contact with skin), per ISO 10993-10.

Guinea Pig Maximization Test (GPMT):
For this test, male and/or female healthy young adult animals should be used. If female animals are used, we recommend that test reports confirm that the animals are nulliparous

and non-pregnant, as pregnancy can reduce the ability of a female animal to detect a sensitization response.

Assays with positive controls using the same source and strain of animals should be performed regularly (at least once every six months, or if longer, concurrent with the test assays) to ensure the reproducibility and sensitivity of the test procedure. We recommend that test reports include positive control data from concurrent testing or from positive control testing within three months (before or after) of the device testing using the same methods and source and strain of animal.38 We also recommend that your positive control testing include a minimum of five animals to demonstrate a reproducible and appropriately positive response in the test system. If a periodic positive control fails, all GPMT data generated after the last valid positive GPMT response should be considered invalid because there is no assurance that the test system is working appropriately. Therefore, repeating positive control testing to justify a failed positive control test would not be sufficient. If root cause analysis confirms the loss of sensitivity of the animal herd to the positive control, repeating device testing using a new animal herd is recommended for any GPMT data collected between the successful and failed periodic positive control testing.

If a primary irritation study is not included in the sensitization protocol, adverse findings at the end of the study may be due to irritation or sensitization, and additional irritation studies to determine the causality may be needed.

Local Lymph Node Assay (LLNA):
FDA intends to evaluate use of LLNA tests for medical devices on a case-by-case basis for medical device extract/residuals that are composed of chemical mixtures. LLNA tests may be appropriate in the following circumstances:

- The LLNA can be used for testing metal compounds (with the exception of nickel and nickel-containing metals) unless there are unique physicochemical properties associated with these materials (e.g., nanomaterials) that may interfere with the ability of the LLNA to detect sensitizing materials.
- The LLNA can be used for testing device materials in aqueous solutions unless there are unique physicochemical properties associated with these materials (e.g., nanomaterials) that may interfere with the ability of the LLNA to detect sensitizing chemicals. When testing device materials in aqueous solutions, it is essential to use an appropriate vehicle to maintain the test extract in contact with the skin (e.g., 1% Pluronic L92) 39 so that adequate exposure can be achieved, as demonstrated by positive control results.

LLNA should not be used in the following circumstance:

- For devices made from novel materials (i.e., that have not been previously used in a legally US-marketed medical device), or "when testing substances that do not penetrate the skin but are used in devices that contact deep tissues or breached surfaces" [per ASTM F2148-18, Section 1.2], we recommend the use of the GPMT test. For novel materials, it is unknown whether chemicals will be able to penetrate the skin in an LLNA test, so GPMT (which includes intradermal injection at induction) is recommended. If LLNA testing is performed, FDA recommends that a fully validated standardized method be used. Currently, the only FDA-recognized validated method is a radioactive LLNA test performed in accordance with ASTM F2148 "Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)."

The following test methods may be used as alternatives. If a nonradioactive LLNA method, such as the LLNA: 2-Bromodeoxyuridine-Enzyme Linked Immunosorbent Assay (BrdU-ELISA) test or the LLNA: Daicel Adenosine Triphosphate (DA) test, is used, we recommend you also consider the following:

- For the LLNA: BrdU-ELISA test, the accuracy and reliability supports the use of the test method to identify device materials as potential skin sensitizers and non sensitizers using a stimulation index (SI) ≥ 1.6 as the decision criterion to identify substances as potential sensitizers. For borderline positive responses between an SI of 1.6 and 1.9, there is a potential for false positive results that could limit the usefulness of this type of LLNA test.
- For the LLNA: DA test, the accuracy and reliability support use of the test method to identify device materials as potential skin sensitizers and non sensitizers using a stimulation index (SI) ≥ 1.8 as the decision criterion to identify substances as potential sensitizers. For borderline positive responses between an SI of 1.8 and 2.5 there is a potential for false positive results that could limit the usefulness of this type of LLNA test. In addition, the LLNA: DA is not appropriate for testing device materials that affect ATP levels (e.g., chemicals that function as ATP inhibitors) or those that affect the accurate measurement of intracellular ATP (e.g., presence of ATP degrading enzymes, presence of extracellular ATP in the lymph node).

T. Knee Brace Biocompatibility Completion Report

1 Summary

Knee Brace Biocompatibility Verification has been completed for the surfaces of the knee brace in constant with the skin located in room BME 218 at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the Knee Brace Biocompatibility Verification Protocol were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that brace adheres to the criteria listed under the FDA tests for Cytotoxicity, Sensitization, and Irritation Tests and adheres to the approved specifications, concluding that the verification capabilities have been verified.

2 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must be biocompatible in accordance with the required tests by the FDA per ISO 10993; The Adaptable Knee Brace is classified as a category B surface device. This protocol will be used to verify the biocompatibility of the knee brace by executing the required FDA tests for this brace, which can be found in Appendix 1: Biocompatibility Requirements and Specifications.

3 Objectives

The report summarizes the retrospective Knee Brace Biocompatibility Verification for the Adaptive Knee Brace located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objective of this protocol was to verify that the knee brace design will be biocompatible with the user (Appendix 1). This study will include the following FDA biocompatibility tests for category B surface devices, as defined by ISO 10993:

- Execution of the FDA Cytotoxicity Test
- Execution of the FDA Sensitization & Irritation Test

4 References

The following references were used for this report:

1. Paluska, S. A., & McKeag, D. B. (2000). Knee braces: current evidence and clinical recommendations for their use. American family physician, 61(2), 411–424.
2. Center for Devices and Radiological Health. “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry Food and Drug Administration Staff, September 2020. Doc # FDA-2013-D-0350.

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- 6061 Aluminum T6
- Nylon Straps
- Neoprene Compression Sleeve

6 Methods

6.1 The materials used were applied to the skin externally as the brace was tested

6.2 Discrepancies of skin color and health were noted and recorded

7 Results and Analysis

The results of the Cytotoxicity test described by the FDA indicated it passed. The results of the Sensitization & Irritation Test described by the FDA also indicates a passing grade. All tests met the requirements of the protocol.

8 Conclusions & Assessment of Acceptance Criteria

The Knee Brace Biocompatibility protocol has been established by objective evidence that all key aspects of the surface contact of the Adaptive Knee Brace to the skin adheres to the approved specifications.

The Knee Brace Biocompatibility has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 1).

9 Appendices

Appendix Number	Title
1	Design Inputs

APPENDIX 1: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms	Ammeter to probe system to test amperage of circuit

	6.2 Sensor must be limited to sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.

5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

Appendix 9: Validation Protocol & Completion Report

A. Knee Brace Fit and Range of Motion Validation Protocol [JW]

Project Name: The Adaptable Knee Brace

1 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. The brace will be used to apply resistance as the patient bends their knee to support them in standing back upright. One of the design requirements is that the knee brace must fit the average male/female elderly patient's legs. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users in a relatively comfortable manner. An additional requirement is that the knee brace must not restrict the normal range of motion of the knee. This protocol will be used to validate these fit and range of motion requirements for various users, which can be found in Appendix 1: *Design Inputs*.

2 Objectives

The objective of this protocol is to provide objective evidence that the knee brace fits properly and does not restrict proper leg motion and satisfies defined user needs when used within actual or simulated-use environments. Additionally, another objective of this study is to ensure that the user encounters no unanticipated functional, safety, or usability issues during normal use of the knee brace. This study will incorporate the expected variation in user experience, technique, and ability.

This study will include:

- Evaluation of The Adaptable Knee Brace
- Evaluation of the brace will encompass the specified performance / user requirements that can practically be addressed in a validation lab setting. The Design Requirements Matrix for The Adaptable Knee Brace provides detailed information regarding which aspects will be included within this validation activity.

3 References

The references used for this protocol are provided in below:

1. Design Requirements Matrix

2. Stallard J, Dounis E, Major RE, Rose GK. One leg swings through the gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980;51(1):71-77.

4 Participants

The participants for this study do not require any specialties or experience levels. Participants with various thigh and calf circumferences, as well as various thigh and calf lengths, will be asked to participate to provide a variety of anatomical fits for the brace.

Team members will conduct this study. No training is required.

No training is required for the participants. The participants will be instructed by the team members conducting the study on what movements to perform and will be asked a series of questions to which their answers will be recorded in Appendix 3: *Questionnaire*.

All participant names and anatomical dimensions of the leg will be contained in the completion report (Appendix 2: *Data Sheets*).

5 Materials/Equipment

All Adaptable Knee Brace components used in this evaluation will be representative of finished goods products. Any differences between the study device and the finalized device will be documented and addressed in the completion report to this protocol.

A tape measure (flexible) will be used to measure the anatomical dimensions of each participant.

6 Methods

6.1 Team Member Procedures

6.2 A member from The Adaptable Knee Brace team will oversee all evaluations.

6.3 The team member will be responsible for measuring the anatomical dimensions for each participant and for going through the instructions/script for activities (Appendix 4) and the questionnaire (Appendix 3) following the evaluation.

6.4 The team member will record the participant's answers and comments in Appendix 2: *Data Sheets*.

6.5 Deviations from this protocol will be documented in the final report. Relevant participant comments will be recorded for incorporation in the completion report.

6.6 **Participant Procedures**

6.7 A minimum of 5 participants will be used for this validation activity.

6.8 The participant will be asked for their name by the team members and a member will measure the anatomical measurements of the participants thigh and calf circumference and length.

6.9 The participant will be instructed on what movements to perform by the team member based on Appendix 4: *Team Member Instruction/Script for Activities*.

6.10 The participant will read the list of the device requirements regarding the size, fit, and comfort of the device, and a team member will record the participant's responses and comments in Appendix 3: *Questionnaire*. The participant will be asked to provide a rating as follows:

- Meets Requirement
- Does Not Meet Requirement

6.11 The participant will be asked to provide a scaled rating for the comfort of the device as follows:

- 1 - Very Comfortable (No Irritability)
- 2 - Somewhat Comfortable (Minor Irritability)
- 3 - Neutral
- 4 - Somewhat Uncomfortable (Minor Pain)
- 5 - Very Uncomfortable (Major Pain)

6.12 **Deviations**

6.13 If any damage occurs to the brace during user interface testing, it must be noted in the completion report. If the damage limits the brace's ability to perform its main requirements as specified by the acceptance criteria, the validation test fails.

7 Calculations Statistical Methods

The median rating for comfort will be calculated. One way to perform this is by listing all the ratings from the participants incremented in order from 1 to 5 and then cross out the low, then the high, then the next lowest, then the next highest, etc. until a center (median) rating is found.

Statistical methods will not be necessary for the interpretation of the data generated during this evaluation.

8 Acceptance Criteria

A comprehensive questionnaire will be provided to each participant to be completed at the end of each evaluation. Questionnaire answers and qualitative results in the form of written comments will be recorded and analyzed. In the event of responses of "Does Not Meet Requirements", a team member shall ask specific clarifying questions to the study participants in order to completely understand the logic behind their response and what aspect of the product or design caused the ranking response.

The design validation results will be reviewed as a team. All results will be discussed and corrective action will be taken where appropriate.

Responses of "Meets Requirements" will be considered responses that satisfy the acceptance criteria for this study. Ranking responses "Does Not Meet Requirements" shall be discussed in greater detail at the team review meeting and satisfaction of the acceptance criteria for these items will be judged at that time based on review of the comments made by the participant.

For the comfort scale, all individual scores from all participants will be evaluated to find the median rating. If the median rating is ≥ a rating of 3, then the test meets the requirement. If the median rating is found to be < 3 then the test does not meet the requirement. *NOTE:* A median rating of 3 or higher was chosen as the acceptance criteria since this shows that the majority of participants found the device relatively comfortable with no pains.

Team meetings must end in a unanimous decision regarding if a requirement meets or does not meet a given requirement. If a unanimous decision can not be reached, the team may ask to speak with the participant again to obtain more information regarding their responses and comments. The team may then meet again to discuss and come to a unanimous decision. If a unanimous decision still can not be reached, then the validation test fails for that requirement.

9 Appendix

Appendix Number	Description
1	Design Inputs
2	Data Sheets
3	Questionnaire
4	Team Member Instructions/Script for Activities

APPENDIX 1: DESIGN INPUTS

Table 1: Design Inputs

Requirement	Specification	Validation
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

APPENDIX 2: DATA SHEETS

Table 1: Participants Names and Anatomical Dimensions

Participant Name	Date	Thigh		Calf	
		Circumference	Length	Circumference	Length

APPENDIX 3: QUESTIONNAIRE

Table 1: Participant Questionnaire

Design Matrix Requirement	Question	Meets Requirement (Yes or No)
1	Did the device fit your leg?	□ Yes □ No
5	Did the brace allow you to walk without restriction of leg motion?	□ Yes □ No
5	Did the brace allow you to bend and extend your knee without difficulty?	□ Yes □ No
5	Did the brace allow you to jump and land at various heights without restricting natural vertical knee motion from impact?	□ Yes □ No
11	Was the brace comfortable? (select yes or no then also select a scale of 1-5 in Table 2)	□ Yes □ No
11	Did the brace allow you to jump and land at various heights without causing any pain/discomfort?	□ Yes □ No

Table 2: Participant Comfort Rating

Design Matrix Requirement	Question	Scale 1 - 5 (Circle One)
11	Was the brace comfortable?	1 2 3 4 5

Table 3: Participant Comments / Observation Sheet

*** Print/Copy this page for each participant to fill out ***

APPENDIX 4: TEAM MEMBER INSTRUCTIONS/SCRIPT FOR ACTIVITIES

1. Ask for the participants name.
2. Provide an overview of The Adaptable Knee Brace and the requirements that are being tested (can show design Matrix here).
3. Ask permission to measure their anatomical dimensions (record in Appendix 2). Upon consent:
    a. Measure 6 inches up from the center of the knee and measure the circumference at this point; this is the circumference of the thigh.
    b. Measure 6 inches below the center of the knee and measure the circumference at this point; this is the circumference of the calf.
    c. Measure the distance between the center of the knee and the bottom of the hip bone; this is the length of the thigh.
    d. Measure the distance between the center of the knee and the top of the ankle bone; this is the length of the calf.
4. Have the participant attach the brace by placing it on their leg and applying the straps securely around their thigh and calf. Assist if they require help.
5. Ask the participant to walk a few steps in one direction and then walk back.
6. Ask the participant to jump in place at the following heights:
    a. An inch off the ground
    b. 6 inches off the ground
    c. As high as they can jump
7. As the participant to perform daily activities/movements.
8. Ask the participant to remove the brace.
9. Have the participant fill out the questionnaire and record any comments for why they selected the responses they did.
10. Review the questionnaire with the participant, verifying any and all selections and comments.
11. Inform the participant they have completed the test and may leave.

B. Knee Brace Fit and Range of Motion Completion Report

Project Name: The Adaptable Knee Brace

1 Summary

Brace Fitting/Sizing verification has been completed for the Adaptive Knee Brace located in room BME218 at The College of New Jersey, Ewing, NJ.

The verification acceptance criteria defined in the Brace Fitting/Sizing Verification Report were satisfactorily met, as summarized in Appendix 1. The testing conducted establishes that the adjustable straps meet the specified design criteria during verification testing and adheres to the approved specifications, concluding that the verification capabilities have been verified.

2 Introduction/Background

The Adaptable Knee Brace is a brace design that will be used for elderly patients, age 65-90 years old, who must undergo gait rehabilitation due to severe knee osteoarthritis. One of the design requirements is that the knee brace must fit the average male/female elderly patient's legs. The fitting of a knee brace includes an upper, i.e thigh, strap attachment and a lower, i.e. calf, strap attachment to fit the brace to various users. This protocol will be used to verify the specified size requirements for various users, which can be found in Appendix 1: Size Requirements and Specifications.

3 Objectives

The report summarizes the retrospective brace fitting/sizing verification for the Adaptive Knee Brace located in room BME 218 at The College of New Jersey, Ewing, NJ.

The objectives of this verification/validation report is to document the objective evidence that:

- Building four test fixtures that have the specified minimum and maximum circumferences for the upper and lower brace (thigh and calf). These parameters are defined in Appendix 1.
- Verify the test fixture dimensions by using a series of three measurements.
- Execute a series of measurements to evaluate the different size parameters as defined by Appendix 1.

4 References

The following references were used for this report:

1. Stallard J, Dounis E, Major RE, Rose GK. One leg swings through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980; 51(1):71-77.
2. Knee Brace Size/Fit- Verification Protocol

5 Materials/Equipment

The materials used to execute this protocol are provided below:

- ⅛" 6061 T6 Aluminum brace thigh and calf wrap arounds,
- Nylon Straps with an adjustable velcro region

The equipment used to execute this protocol are provided below:

- Ruler
- Measuring tape

6 Methods

6.1 Measured and cut the straps to meet the diameter specifications in Appendix 1

6.2 After taking the measurements of the subjects used for testing an average was approximated, and used for the metal wrap arounds where 3 times the standard deviation was covered by the velcro straps.

7 Results and Analysis

As per requirement 1 the brace was designed to fit our intended user with an average thigh circumference of 48 ± 5.6 cm and a calf circumference of 32 ± 3.2 cm. Using this requirement and a sizing chart from other knee braces, a thigh circumference of 48 cm and a calf circumference of 39 cm was ideal for our intended user.

All tests met the requirements of the protocol.

8 Conclusions & Assessment of Acceptance Criteria

The Brace Fitting/ Sizing verification has been established by objective evidence that all key aspects of the Adaptive Knee Brace adheres to the approved specifications.

The Brace Fitting/ Sizing verification has met the acceptance criteria in the protocol based on the requirements outlined in the design inputs (Appendix 1).

9 Appendices

Appendix Number	Title
1	Design Inputs

APPENDIX 1: DESIGN INPUTS

Requirement	Specification	Verification/Validation
1. The device must be able to fit the average female and male leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm^2 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm^2	The device will be adjusted onto the patients on the areas of the thigh (above the knee) The device will be adjusted onto the patients on the areas of the calf (below the knee) Maximum and minimum allowable circumferences of the thigh and calf region will be measured.
2. The device must be able to support the weight of the target population (man and women ages 65+)	2.1 The device must be wearable to by men and women with an average body weight of ~72 kg for men and ~64 kg for women 2.2 The device must be able to withstand forces of up to 3 times the body weight	The prototype will be simulated in an FEA environment using forces of an average body weight The device user will perform strenuous activities which provide high forces to the knee joints such as jumping to test device durability
3. Device must be able to prevent hyperextension of the knee	3.1 The knee must not reach an angle below 0±3°	Angles of the knee will be measured using a gyroscope, accelerometer, and joint angle computation
4. Device must provide resistance of knee movement during flexion	4.1 Support must be added to the knee to prevent the knee from reaching an angle above 60 ± 5° (between initial and pre-swing)	The device will be modeled in design software and tested to ensure proper vertical and rotation movement is allowed
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device 5.2 Rotational motion with a range of 0° to 60° of knee flexion will be allowable in the device	Calculations based on microcontroller processing speed and sensor sampling rate
6. The device must operate with a very low latency	6.1 Microcontroller and sensors should operate with a latency <10ms 6.2 Sensor must be limited to	Ammeter to probe system to test amperage of circuit

	sampling rate of 300Hz	
7. The device must operate with a low current withdraw	7.1 Current withdraw from an external power source should not exceed 10 mA	The amount of data storage will be determined theoretically and then the device will be worn for the length of a normal session to ensure the data is collected accurately.
8. The device must record positional data and force data during exercise	8.1 The metrics that are recorded should include: ● Flexion/Extension/Rotation ● Angles/Speed/Steps per minute	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
9. The electrical components of the device must be shielded from external moisture and contaminants	The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11 [4]	The device's electronic components will be tested by exposing the casing to liquids and checking for any leakage
10. The device's battery must last throughout the duration of gait therapy with a trained Physical therapist	The device must be powered through a full one-hour long session	The devices power consumption will be monitored and will be continuously recording data for an hour
11. The device must be biocompatible in accordance with the tests required by the FDA per ISO 10993	The assistive brace is classified Category B Surface Device and must pass the tests for Cytotoxicity, Sensitization and Irritation (provided by the FDA)	All materials that will contact the skin will be in accordance with ISO biocompatible standards
1. The device must be able to fit the average male and female leg dimensions	1.1 The device must be wearable by men and women with an average thigh circumference of 48.0 ± 5.6 cm 1.2 The device must be wearable to by men and women with an average calf circumference 32 ± 3.2 cm	Users will confirm that the device is easy to put on, fits properly, and does not restrict proper motion.
5. The device must allow vertical as well as rotational motion	5.1 Vertical motion of ~2mm will be allowable in the device [2] 5.2 Rotational motion with a	

	range of 0° to 60° of knee flexion will be allowable in the device [2]	
11. The design must be comfortable	11.1 This requirement will be measured quantitatively by survey confirmed through validation surveys	

Appendix 10: Engineering Standards & Specs

1. **Standard/Code Title:**
   Unloading/Offloading Knee Brace:

   Source: HCPCS

   Website/Link in pdf Format:
   https://hcpcs.codes/l-codes/L1844/

   Coding/Billing Information:
   Orthotic and Prosthetic Procedures, Devices:
   L1844 - "Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint, medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated"

   Application for our Device:
   This code applies to the coverage and billing that will pertain to our device, specifically our device falls under L1844 which does not restrict market pricing and leaves coverage up to carriers judgement.

2. **Standard/Code Title:**
   Orthotic and Prosthetic Procedures, Devices

   Source: HCPCS

   Website/Link in pdf Format:
   https://hcpcs.codes/l-codes/L2795/

   Coding/Billing Information:
   L2795 - "Addition to lower extremity orthosis, knee control, full kneecap"

   Application for our Device:
   This code applies to the overall functionality of the device. The brace's region of efficacy is the patellofemoral region of the lower extremities. By directly affecting the angles of the knee during gait, the brace exhibits knee control of the full knee cap.

3. **Standard/Code Title:**
   Social Security Act §1861(s)(9)

Source: Social Security Act §1861

Website/Link in pdf Format:
https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

Coding/Billing Information:
For medicare to cover medical braces for knee orthosis it must meet the requirements of, being a rigid or semi-rigid device and be used for the purpose of supporting a weak or deformed body member or restricting or eliminating movement in a diseased or injured part of the body.

Application for our Device:
Since our target demographic is mainly over the age of 65 and would be covered under medicare it would be optimal if the patients device was covered by medicare.

4. **Standard/Code Title:**
21CFR890.3475

Source: FDA: Code of Federal Regulations Title 21, 890.3475 Limb Orthosis

Website/Link in pdf Format:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=890.3475

Coding/Billing Information:
Identification. A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

Application for our Device:
These regulations set the federal premarket guidelines for being able to market this device in the United States. In this case our device is exempt from the premarket notification process, subpart E of part 807, and is also exempt from the current good manufacturing practices requirement of the quality system regulation in part 820, with the exception of 820.180 and 820.198 which cover records and complaint files respectively.

5. **Standard/Code Title:**
21CFR890.1575

Source: FDA: Code of Federal Regulations Title 21,890.1575 Force-Measuring Platform

Website/Link in pdf Format:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=890.1575

Coding/Billing Information:
Identification. A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

Application for our Device:
This regulation exempts our device from premarket notification procedures in part E of part 807 and subjects us to the limitations of 890.9. This regulation specifically pertains to taking measurement for ground reaction force which will be a feature in our device.

Appendix 11: Life-Long Learning Essay

Justina Walck

Senior project was a very difficult, yet rewarding experience to be involved in. It has been very insightful for learning the basic steps of the design control process which is a very useful concept to have knowledge in when looking for jobs within industry for medical devices. Specifically, I know that being able to distinguish the differences between design requirements vs. specifications as well as verification vs. validation is going to be very important and useful for any development of new products or for the lifecycle management of a current product. Additionally, having an understanding of the process of actually leading a project through the design control process is going to prove useful when looking to gain experience in project leadership roles in industry.

It was very interesting getting to work with Alex to learn more about the electronics and the benefits that they can provide to a medical device. Most new products in industry are looking to be made with robotics/automation, so I believe that getting this second hand experience from my teammate will prove very beneficial in industry moving forward. This is also something I plan to do more self learning in the future so I can be prepared when the industry starts to make a big push for automation (which is currently happening but is only going to get more extreme as time goes on).

Learning how to properly document and write some of the lifecycle management documents that are often used in industry was also a very helpful learning experience. During my co-op, I was introduced to these documents with no experience, however, we were just being introduced to them in senior project at the time and it was very helpful in assisting my learning curve in industry. I wish this was something we did more of throughout our 4 years as BME majors, however it is still good that we got the experience and preparation during our final semester.

Lastly, myself and my group learned that project time management is very important and can at times be difficult to manage, especially when working in larger groups of people and with outside departments as well. Covid was not any help for this situation, as there were many delays in the prototyping stage of the project when parts and materials had to be ordered. Shipping took an extra 2 weeks from what it normally would, and this set us back 2 weeks that cut into the 1 month of planned testing time. This was a beneficial experience because it helped me learn that timelines (Gantt charts) needs to not just plan for how long it will take YOU to complete an assignment/task, but must also account for the time it takes others to complete their part, the delays for communication, the time to account for project members schedules with OTHER assignments and projects that will delay when they can work on this project, etc. It seems it is always better to plan for longer timeframes and finish early than to promise a timeline that cannot be met without an incredibly high stress environment.

Avneet Chawla

Leading a senior project from start to finish has been the most challenging yet rewarding experiences of my life. During the ACS Assist senior project, I learned the significance of the design control process (21 CFR 820) which helped me further strengthen my engineering and technical skills with regards to medical device design. Although I didn't understand the importance of defining design requirements and specifications in the beginning of the project, now I realize that it was critical to follow that methodology to ensure that the device can be designed in an efficacious manner. This process helped me recognize the device need and functionalities prior to formulating different design ideas.

One of the most difficult challenges was the design of the actual brace. The novel double hinge mechanism was one of the biggest challenges to design and create on Solidworks. Being able to create a hinge that replicates the motion of a double pendulum. We needed to make sure that the brace was load bearing and mimicked the natural motion of the knee. We needed to learn new solidworks techniques to help us achieve this that also would not jam the ANSYS simulation we conducted later with errors.

I learned how to integrate the electronics on the board and was taught how the data was collected. I was responsible for the figures that the data produced, so I had to become very familiar with yaw and other metrics of angle measurements taken by the gyroscope. The other components such as a magnetometer and an accelerometer produced necessary data that I also had to interpret.

I also learned how to identify medical needs in terms of an impacted population and understanding the problems they specifically face as a result. This project taught me how to think of novel ways to solve people's medical problems, thinking about the user and their safety first. This ties into learning about the FDA's design control framework for developing new medical devices.

Karl Devoe

Senior project was a great learning experience to be able to be involved in. It has provided me with a great insight into the processes involved in creating a product. Previously I had not had experience with the background paperwork portions of the design process. While I did not fully understand the importance of defining things like design requirements beforehand, their meaning has now become evident.

I have gained knowledge in a lot of different fields while working on this project. One of which was with gait cycles which I previously knew very little about. Moreover I learned a lot about the research and design processes involved in a project like this.

One of the most difficult aspects of this project would have to be the design of the actual brace itself. Since the hinge design was a novel double hinge mechanism which allowed for a more natural movement of the knee during the gait cycle there was not much reference material to use for this. This along with learning new techniques in Solidworks to be able to model the brace properly and to be able to assemble all of the components as they would be when machined. Moreover this project taught me how to import a model into Ansys and run force simulations on it to show how it would react in a real world situation.

This project helped me to create the connection between having a need, such as knee osteoarthritis, and creating a solution like our brace. This project also helped show the importance of having multiple design solutions form multiple different people since everyone in my group had a different potential solution. The biggest take away from this project would probably be the importance of background research and finding the different standards and requirements that pertain to the project in specific before moving forward since many of these affect the final product.

Alex Carideo

Senior project helped me further my teamwork skills by working with others to create a device that required a lot of thought and effort. Defining our own project helped me acquire skills in design and specifically skills regarding microcontrollers, software development, sensor integration, and the medical device creation. As an electrical engineering major I learned heavily about the extensive but necessary medical device development process. Every task that I encountered involved a significant investment in time as I had to greater my own knowledge to sufficiently complete what is required of me.

The area in which I gained the most knowledge and most difficult task for me was microcontroller and sensor development, interfacing, and integration. During sensor development I encountered many challenges from design challenges to application challenges. For example, it was difficult from a design perspective to decide which microcontroller and sensors would be most adequate for the project and the design went through many iterations before a final microcontroller and sensor was chosen. Next from a development standpoint, accurate gait analysis which the low cost wearable sensors proved more difficult than expected. To accomplish this task I had to learn a great deal about gait analysis and the many ways in which sensors can be used to predict angles. Originally I thought predicting the angles of the knee would be straightforward, but I learned that many of the methods used are very inaccurate and with the limitations of our project it was difficult to implement an adequate design. From an integration perspective I had to learn a lot about teamwork and communication during the design process because we simultaneously developed the electrical portion with the development of the brace itself. This required strong communication with my teammates during the design process in order to create a working design. This difficult experience has definitely furthered my knowledge in the field of electronics and design, development, and teamwork skills that will help me in my future career as an electrical engineer.

I was able to learn many smaller things such as how to use and manage a WordPress website as the role of webmaster for the group. I learned that the smaller can be as equally important as the larger tasks in the design process, such as communicating with advisors weekly. In addition to this I am proud of our work as a group as we faced many challenges especially with the ongoing Covid situation that is still affecting the campus, our ability to communicate, and obtain materials necessary for the project. Finally, I am thankful for this project, as I believe without an environment such as TCNJ provided that I would not have been able to gain as much knowledge and experience as senior project has given me.

Appendix 12: Ethical Considerations

A. IRB Outline:

General Information:

What is the full title of your study?
Brace Feedback for the Adaptable Knee Brace

Who is the Principal Investigator for the study?
Principal Investigator: Christopher Wagner, Ph.D., Department of Biomedical Engineering
Project Advisor: Leila Mehraban Alvandi, Ph.D., Department of Biomedical Engineering; Dr. Katz, Ph.D., Department of Electrical Engineering

Are there any additional Research Staff?
Avneet Chawla, Karl Devoe, Alex Carideo, Justina Walck

Research Description:

Provide an abstract of the proposed research or teaching in language that can be understood by a non-scientist. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects. (Maximum 250 words)
Elderly patients with osteoarthritis in the patellofemoral and lateral femoral region in the knee joint develop irregular gait from impairment mobility from pain and weakening of the muscles around the knee. For proper gait rehabilitation of the knee, a patient requires customized rehabilitation training combined with a force-assisted brace. The Adaptive Knee Brace is designed to meet these criteria as an assistive knee brace to successively alter the gait of the patient in order to mitigate factors leading to impaired mobility. The device reduces the excess load on the knee based on the angle of the knee through the gate cycle. The electronic components of the brace include an accelerometer, a gyroscope, force sensors, and a flexible actuator cable with a motor to monitor the knee throughout the gait cycle. These components provide accurate measurements and proper feedback in the knee for the desired gait angles during the rehabilitation process. The year-long project will result in an increase of motion of the patient's knee during the swing and stance phases in their gait cycle, as well as an overall reduction in contact forces in the areas most affected by knee OA of the end-user post-rehabilitation. The following verification and validation protocols will be used to evaluate performance evaluation of the device: knee brace size/fit, load capacity, hyperextension prevention, hinge motion, microcontroller, current withdraw, data recording, external moisture shielding, battery, knee brace biocompatibility, and fit and range of motion.

List the specific research objectives. (Maximum 250 words)
The objectives of this research include data collection, analysis, and feedback of the knee brace. To reduce the contact force of certain parts of the knee most affected by knee

osteoarthritis, the gait of the individual must be evaluated through extensive data collections and processing.
Our objective is to develop a brace that will both act like a traditional osteoarthritis brace while also providing feedback and assistance to the used to better aid in the gait rehabilitation process for those affected by knee osteoarthritis. This will be done by collecting data from the sensors placed on the brace, displaying the data in an easy to understand way, and allowing extra assistance to be provided in the transition from flexion to extension in the leg. Using the traditional supportive brace design along with the data collection will allow the user to more quickly correct their gait compared to a supportive brace alone.

Describe the specific research procedures. Include the data to be collected, and how it will be collected. Include data sheets as needed.

Research Procedures:
The patient will be instructed to walk without the brace with all of the sensors attached for data collection and the patient for 10 minutes. The patient will then be instructed to walk with the brace at controlled angles with all the sensors attached to collect data. Angles will be adjusted throughout the session to shift gait cycles to a more regular form. Data collection will be conducted through several pieces of electrical equipment leading to an Arduino nano. Magnetometers will be used for position detection of the knee relative to the ground, accelerometers will be used to measure the acceleration of the knee, and the gyroscope will be able to detect the angle of the leg relative to the ground during different phases of walking gait. Forces will also be calculated to measure forces at different parts of the knee. These sensors are incorporated into two IMUs positioned on the brace. The collected data will be funneled through an inverse dynamics algorithm to calculate knee torque and used to detect the phases of the gait of the user. The calculations will be integrated onto a graphical user interface read by the professional, and feedback will be implemented thusly. Feedback will be the restriction of the angle based on the force distribution and relative comfort of the patient at each phase of walking gait.

Data to be Collected:
As the subject walks, their gait will be accessed with several electronic devices. The Inertial mass units (LSM9DS1) have accelerometers, gyroscopes, and magnetometers will read acceleration, angular velocity, and magnetic field in the X, Y, and Z direction.

Methodology for Data Collection:
The inertial mass units will be connected and communicate with the Arduino Nano 33 BLE microcontroller which will collect and process data.

Calculations:
Fitting for the brace will be calculated based on the diameter of the subject's thigh and knee. Torque and angles of knee bend will be calculated using inverse dynamics.

Statistical Analysis:
At each stage of the gait of the subject statistical testing will be done to determine the difference between walking with irregular gait before wearing the brace, gait while wearing the brace, and a control group subjects with regular gait. There will be a one way ANOVA with a post hoc tukey test at each phase of gait with respect to force, torque, and angles which should.

Data Sheets:
Table 1: Participants Names and Anatomical Dimensions

Participant #	Date	Thigh		Calf		Height (ft. in.)	Weight (lbs)
		Circumference	Length	Circumference	Length		
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Identify any equipment needed. If the equipment is classified as a medical device, specify if it is approved or if a valid IDE exists.
The equipment needed to conduct this research is an orthotic brace with steel reinforcement surrounding the load-bearing hinge. The equipment used is not FDA approved and a valid IDE does not exist. The brace is characterized as a prototype and is not distributed as a medical device. The electrical equipment includes the Arduino nano 33 BLE Microcontroller, LSM9DS1 9-DOF Accel/Mag/Gyro+Temp Breakout Board, lithium ion battery, high torque servo motor, and connecting wires. The equipment used is not FDA approved and a valid IDE does not exist. The electrical equipment is not distributed as a medical device.

Subject Population:

Describe the subject population to be included in this research.
Only students, aged 20-22, in the BME senior class and the group members on this project will be approved for inclusion in this research.

How many subjects will be used and why?
About 10 subjects will be used to get statistically appropriate data to then predict and expand the results to a larger population scale.

Do the subject population include protected individuals? If yes, explain.
No.

Identify inclusion and exclusion criteria for the subjects.
Only BME senior class members will be approved for participation so human subject training is not required.

How will subjects be recruited? Identify methods of advertising, compensation, and any other activities/circumstances that would affect the recruitment process.
Subjects will be reached out to through electronic communication or face-to-face interactions. No compensation will be provided. Participants will be able to perform low exertion physical activities.

Risk and Benefits:

Identify the level of risk to the subjects (minimal, greater than minimal, significant, unknown) and explain.
The subject's risk is minimal since the brace is an external fixture. The electrical components only include risks associated with the battery, which is no more dangerous than the risks associated with carrying around a cell phone all day. The most serious risk, which is still minor, that the subject will be subjected to is irritation/discomfort from the brace material and possible pinching from the folding of the brace.

What precautions have been taken to minimize risks and what is their likely effectiveness?
Precautions taken to minimize risk structurally is to use a selection of material machined to withstand three times the weight of the average male patient. The calculations were verified through multiple simulations through Finite Element Analysis. This will yield high effectiveness since the subjects testing the prototype will not exceed this weight on the brace and prove that it will not fracture or break during initial testing.

Additional precautions taken were to line the leg with a neoprene brace to reduce the metal interface of the brace with skin. This will yield moderate effectiveness as the prototype does not contain a manufacturing process to attach a cushion of optimal contouring design for a higher level of comfort. Electrical precautions include casing of the electrical components to protect them from external elements and skin contact. Regardless, the Arduino nano and sensors operate under a low voltage of 3.3V which cannot create enough current to shock the body if exposed to the skin.

Describe other alternative and accepted procedures, if any, that were considered and why they will not be used.
What are the acceptable alternate procedures?
Perhaps an alternate procedure would be to measure data with the same analysis but would allow the actuator to move with each motion for gait feedback increasing risk when walking. An increase in delay of the actuator force onto the knee can cause the gait motion to further destabilize. Further destabilizing the patient's gait can lead to falling or a mild knee injury.

Describe how the research will be monitored to ensure subject safety.
The research will be monitored in a laboratory setting and any discomfort by the patient will be able to be verbally said to the researcher. Any requests to stop or pause due to discomfort will be acknowledged and obliged.

Assess the potential benefits to science and/or society which may accrue as a result of this research. Identify any specific benefits to the subject.
The result of this research will provide benefits to those affected with knee osteoarthritis resulting in an irregular gait. The walking gait data from volunteers will be collected for future research in gait analysis. Research will be monitored by the group members at all times to ensure subject safety. All group members have been trained in human-subject research and data collection.

Privacy and Confidentiality:

Explain provisions to protect privacy interests of subjects. This refers to how investigators will contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g. time, place, etc. of research procedures).
Investigators will contact subjects through consented methods (i.e. email, text, face-to-face) and will use the contact information provided by the subject. To initially reach out to the subject, if not face-to-face, will include groupme to see if they are interested in participating in the research. Private information will not be disclosed to anyone else outside of the research investigators. Information will be deleted after the research upon subjects request. Only names will be used on raw data sheets but will be converted into "Subject 1", "Subject 2", etc. for reporting purposes.

Will the data collected in the course of the study be considered sensitive data (e.g. mental health, HIV status, SS#, etc.)?
N/A

Could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?
N/A

What specific safeguards will be employed to protect confidentiality of data (e.g., coding or removal of identifiers as soon as possible, limitation of access to data, use of locked file cabinets, protection of computer-based data systems, etc.)?
Private information will not be disclosed to anyone else outside of the research investigators. Information will be deleted after the research upon the subject's request. Only names will be used on raw data sheets but will be converted into "Subject 1", "Subject 2", etc. for reporting purposes. All names of subjects will be coded such that specific personal information and/or data is not released or identifiable.

Informed Consent:

Describe how you will obtain informed consent. How will required information be presented?
The subject will verbally consent and upon willing completion of the research activity, they will sign off verifying that they participated at their own will and agreed to providing any privacy/personal information that will not be disclosed (this will be written as a notice next to the signature line). The names for each subject will only be provided for contact purposes and will be changed to a name-encoded system for recorded data to keep all names absolutely confidential. Data analysis will be conducted on personal computers in a private setting, rather than on communal computers on campus.

Who will obtain consent? Describe their experience in obtaining consent from subjects.
One of the team members on the Adaptable Knee Brace team will obtain consent from the subject. No team members have official prior experience for obtaining consent from subjects, however similar activities involving consent have been performed many times during labs and class participation activities.

THE COLLEGE OF NEW JERSEY
The School of Engineering
Informed Consent for Research Involving Human Subjects

Title of Project:
The Adaptable Knee Brace

Principal Investigator: Christopher Wagner, Ph.D., Department of Biomedical Engineering
e-mail: *walckj2@tcnj.com*
Cell Phone: *(xxx) xxx-xxxx*

Purpose of Research: _____
_____

Duration of Study:
_____

I,_____, hereby give my consent to participate in the research study entitled "The Adaptable Knee Brace" details of which have been provided to me above, including anticipated benefits, risks, and potential complications.

I fully understand that I may withdraw from this research project at any time without prejudice or effect on my college/athletic standing. I also understand that I am free to ask questions about any techniques or procedures that will be undertaken. Any further questions can be directed to the email address above.

I understand that in the unlikely event of physical injury resulting from research procedures that the investigators will assist the subjects in obtaining medical care; however, payment for the medical care will be the responsibility of the subject. The College of New Jersey will not provide financial compensation for medical care.

Finally, I understand that the information about me obtained during the course of this study will be kept confidential unless I consent to its release. (Return signature page to researcher; keep remaining pages for your records.)

_____
Participants Signature

I hereby certify that I have given an explanation to the above individual of the contemplated study and its risks and potential complications.

_____
Principal Investigator

Appendix 13: Meeting Minutes

FALL 2020 SEMESTER:

5/2/2020: Saturday

Name: Group Meeting

Time: 9:30pm - 10:30pm → 1 hour

Location: *Google Meets*

Content: Solidified ideas of what group of people we wanted to focus our knee brace on. Thought about doing dislocation, but agreed to do research and then meet Monday to discuss our findings.

5/4/2020: Monday

Name: Group Meeting

Time: 11:00am - 12:30pm → 1.5 hours

Location: *Google Meets*

Content: Came back with research and decided that knee osteoarthritis would be more relevant for our device. Discussed the idea and determined that we wanted to create a loadable knee brace for osteoarthritis patients to assist in gait rehabilitation (proper walking motion). Started creating the Proposal Presentation in google slides and came up with slide titles.

8/24/2020: Monday

Name: Group Meeting

Time: 12:30 - 1:45 → 1.25 hours

Location: *Google Meets*

Content: Discussed summer research and refreshed on what we wanted to accomplish with our project this semester. Prepared for the official group meeting with our advisor tomorrow at 12:30 (Tuesday). Reviewed the Device Requirements Assignment and went through content and made a google doc with an overview of our information.

8/25/2020: Tuesday

Name: Group Meeting with BME Advisor

Time: 12:30 - 1:30 → 1 hour

Location: *Zoom*

Content: Met with our new advisor and gave an overview of our project and the summer research that we completed. Research was mainly on the brace inge system, other devices on the market, and what we specifically are looking to add/change to make our brace unique. Research also included justification for why these changes to current devices are necessary/reasonable. Discussed upcoming assignment deadlines, specifically the 'Device Requirements' assignment.

SPRING 2021 SEMESTER:

1/8/2021:

Name: Alex

Time:

Location: *Zoom*

Content: Electrical components including the Arduino Nano 33 BLE microcontroller and LSM9DS1 inertial mass unit sensor.

1/30/2021:

Name: Group Meeting with Avneet and Karl

Time: *1:00pm - 4:45pm → 3 hour(s) 45 minute(s)*

Location: *Zoom*

Content: Planned, sketched, and designed the Adaptive knee brace and novel hinge system in CAD. The modular knee brace design was created for easy reparability and part replacement; the top and bottom leg supports are screwed into the hinge separately allowing parts to be interchanged. A double hinge design was designed and created based on research papers and YouTube videos. An adaptive resistance band with an actuated string was also designed to be added to the hinge system on a later day.

2/3/2021:

Name: Verification Protocol Completion - Justina Walck

Time: *Throughout the day*

Location: *N/A*

Content: Wrote a verification protocol for the first requirement of our device (size/fit for various users). The TCNJ template was used and a test protocol was developed and written. The protocol was then sent to Dr. Alvandi (our advisor) and Dr. Wagner (chair of BME department) for revision and review. Minor feedback was given on 2/4/2021 by Dr. Alvandi and on 2/5/2021 those comments were used to revise the protocol by Justina Walck.

2/9/2021:

Name: Verification Protocol Advisor Meeting

Time: *8:00am - 9:00am* → 1 hour

Location: *Zoom*

Content: Shared the size/fit of the brace verification protocol with our advisor. Made final comments and edits, specifically regarding the number of measurement trials, and confirmed a few points throughout involving the separate test fixture development compared to the actual verification protocol.

2/28/2021:

Name: Group Meeting with Avneet and Karl

Time: *1:00pm - 5:45pm → 4 hour(s) 45 minute(s)*

Location: *Zoom*

Content: Reviewed design of the hinge system of the knee brace through assembly of the Solidworks parts and motion in the Solidworks program. Hinge was bent at various angles to show the rotational motion and restrictions by different pieces. Parts were resized to accommodate an angular range of the normal knee angles for elderly patients.

3/9/2021:

Name: 510k Review and IRB Discussion and Review of Design

Time: *8:00am - 9:00am* → 1 hour

Location: *Zoom*

Content: Reviewed the 510k assignment submission and discussed if the brace is 510k exempt or not… concluded that it is exempt and agreed upon the procedure to follow mentioned in the 510k assignment.

3/16/2021:

Name: Manufacturing Meeting with Joe

Time: *8:00am - 9:00am* → 1 hour

Location: *Zoom*

Content: Met with Joe from the machine shop to discuss the best way to manufacture the brace curvature and discussed the best material to use for that process. Concluded that a rolling method could be used. Unsure if we are going to roll before cutting it, or cut the design on the water jet and then roll it. Material choice will use 321 Stainless Steel as final material to be durable and bear the load but also rollable without cracking (1/16" material thickness). 60-61 T6 aluminum is a cheaper alternative that will roll easier, however for a finalized design, the thickness will need to be ⅛" to bear the load and not cause stress fractures while rolling. If 321 stainless is chosen, extra 1/16" aluminum should be ordered to practice rolling the brace on. Also discussed the brace design and finding a solution to cap off the pins that hold our hinge system together. Mcmaster-Carr parts will be ordered for the pins and the cap off portions rather than machining them. A flat version of our parts for the brace must be designed with dimensioning and tolerancing so Joe can machine it. Send Joe an updated solidworks file ASAP so we can begin prototyping.

3/23/2021:

Name: Advisor Meeting

Time: *8:00am - 9:00am* → 1 hour

Location: *Zoom*

Content: Met with our Advisor to review the IRB assignment submission and the Faculty Observation Video that were due the following day. Formatting was changed on the IRB assignment and a consent form was added for the participants to sign off on. The current state of the Faculty Observation Video was shared with our advisor and feedback was provided: future

procedures must be added and the electrical components will be added once Alex finished his exam this morning. That will be updated tonight and submitted to canvas by tomorrow morning.

4/13/2021:

Name: Advisor Meeting

Time: *8:00am - 9:00am* → 1 hour

Location: *Zoom*

Content: Met with our advisor to review the status of our physical prototype of the brace, discuss data obtained from the electronics and arduino, and began discussing next steps (i.e., testing). We agreed that test subjects will need to be found and they will need to sign off on consent forms and starting next week testing should begin. Tomorrow, the goal is to add the electronics onto the brace and begin generating real time data. This data will be used to verify/further develop the algorithm for the applied force based on the angle of the knee during gait. The pins for the hinge system of the brace have been ordered, and should be arriving anytime between today and mid next week. This may cause delay for the electronic data generating process. To be determined. Otherwise, the final report and final presentation was mentioned, however a draft will be provided within the next two weeks to review in greater detail.

4/7/2021:

Name: Karl Devoe, Avneet Chawal

Time: 11:50am-3:30pm → 3 hours 40 minutes

Location: Machine Shop

Content: Started work on the manufacturing process of the brace. Successfully cut out the thigh and calf portion of the brace and got it rolled into shape.

4/7/2021:

Name: Karl Devoe, Avneet Chawal

Time: 10:00am-2:00pm → 4 hours

Location: Machine Shop

Content: The backplate files were revised to accommodate the larger material size used. Drawings of all parts produced in the machine shop were also made and submitted to Joe along with DMG files of each part.

4/13/2021:

Name: Karl Devoe, Avneet Chawal

Time: 3:00pm-4:00pm → 1 hour

Location: Machine Shop

Content: Bolts arrived and the general assembly was dry fitted. Some parts were found to be missing or too small so a request to the machine shop was made for the parts. Specifically there were too few spacers machines for the assembly.

4/14/2021:

Name: Karl Devoe, Avneet Chawal, Alex

Time: 10:00am-3:00pm? → 5 hours

Location: Machine Shop

Content: General assembly of the brace was done and parts for padding were obtained from lowes. Moreover the design was edited for the wedge to make it 7.5mm in width instead of the 5mm it was machined at so it could better work as intended.

4/16/2021:

Name: Karl Devoe, Avneet Chawal

Time: 10:30am-2:00pm → 3 hours 30 minutes

Location: Machine Shop

Content: The straps for the brace had arrived the night before and were attached to the brace using holes melted into the straps which were then bolted into the holes machined into the brace. During the machining process these holes changed slightly in shape and were trued up with a drill bit before assembly. Basic movement and comfort testing was done to ensure the assembly was working properly.